U.S. DEPARTMENT OF COMMERCE
National Technical Information Service
PB-283 559

Ninth Annual National Conference on Radiation Control - Meeting Today's Challenges, Held in Seattle, Washington, on June 19-23, 1977

Bureau of Radiological Health, Rockville, Md.

Prepared for

Conference of Radiation Control Program Directors, Inc.

Apr 78

BIBLIOGRAPHIC DATA SHEET

1. Report No. FDA/BRH-78/89

2.

3. Recipient's Accession No. PB283559

4. Title and Subtitle
9th Annual National Conference on Radiation Control - Meeting Today's Challenges

5. Report Date
April 1978

6.

7. Author(s)
n/a

8. Performing Organization Rept. No. FDA 78-8054

9. Performing Organization Name and Address
Department of Health, Education, and Welfare, PHS, Food and Drug Administration, Bureau of Radiological Health
5600 Fishers Lane, Rockville, Maryland 20857 (HFX-25)

10. Project/Task/Work Unit No.

11. Contract/Grant No.

12. Sponsoring Organization Name and Address
Cosponsors: Conference of Radiation Control Program Directors, Inc., Environmental Protection Agency -Office of Radiation Programs; U.S. Nuclear Regulatory Commission; and U.S.DHEW, PHS, FDA, Bureau of Radiological Health.

13. Type of Report & Period Covered Proceedings of Conference -6/19-23,1977

14.

15. Supplementary Notes

16. Abstracts

This publication contains the proceedings of the 9th Annual National Conference on Radiation Control - Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference of Radiation Control Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces are included in these proceedings.

17. Key Words and Document Analysis. 17a. Descriptors

Atomic Energy Act; BENT; CT scanning; genetically significant dose (GSD); laser; mammography; nonionizing; nuclear medicine; personnel dosimetry; quality assurance; radiation; risk factor; ultrasound; x ray.

17b. Identifiers/Open-Ended Terms

APPROVED FOR UNLIMITED RELEASE
William L. Jackson DATE 1/31/78
WILLIAM L. JACKSON
DIRECTOR, FDA/PRDC (NTIS)

17c. COSATI Field/Group

18. Availability Statement
Unlimited

19. Security Class (This Report)
UNCLASSIFIED

20. Security Class (This Page)
UNCLASSIFIED

21. No. of Pages 429

22. Price A19-A01

FORM NTIS-35 (REV. 3-72)

THIS FORM MAY BE REPRODUCED

USCOMM-DC 14952-P72

PB 283 559

Conference of Radiation Control Program Directors, Inc.

9th Annual
NATIONAL CONFERENCE ON RADIATION CONTROL

Meeting Today's Challenges

June 19 - 23, 1977
Seattle, Washington

Published by

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U. S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

BRH TECHNICAL PUBLICATIONS

Publications of the Bureau of Radiological Health and its components are available in paper copy from either the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, D.C. 20402 (there is a $1.00 minimum for mail orders), or the National Technical Information Service (NTIS), Springfield, VA 22161, as indicated. Order by GPO or PB numbers, as appropriate. Each document receives an initial publication price which is subject to change. The documents are also available in microfiche at $3.00 from NTIS. There is a surcharge of $2.50 per copy for foreign requests. The NTIS will automatically distribute Bureau publications as microfiche for $0.65 per report to those who subscribe to its "Selected Research in Microfiche" program. Bureau publications are coded as "HFX." A deposit account with NTIS is required. Publications without a GPO or PB number indicated are only available without charge from the BRH Technical Information Staff (HFX- 25), 5600 Fishers Lane, Rockville, MD 20857.

FDA 76-8056	CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1975 (PB 257 937/AS, $6.75).
FDA 76-8058	Quadrennial Report of the Division of Biological Effects (PB 258 436/AS $6.75).
FDA 76-8061	Uranium in Dental Porcelain (GPO 017-015-00113-0, $0.75) (PB 259 624/AS, mf only).
FDA 77-8001	BRH Routine Compliance Testing for Diagnostic X-Ray Systems (PB 261 082/AS, $9.25).
FDA 77-8002	Symposium on Biological Effects and Measurement of Light Sources (GPO 017-015-00114-8, $3.30) (PB 261 167/AS, mf only).
FDA 77-8003	First Image Receptor Conference: Film/Screen Combinations (GPO 017-015-00115-6, $2.50) (PB 261 166/AS, mf only).
FDA 77-8004	Biological Effects of Ionizing Radiation: An Overview (GPO 017-015-00117-2, $0.65) (PB 262 453/AS, mf only).
FDA 77-8005	Report of State and Local Radiological Health Programs, Fiscal Year 1975 (PB 259 947/AS, $4.50).
FDA 77-8006	Nationwide Evaluation of X-Ray Trends: Organ Dose Index System-Instruction Manual.
FDA 77-8007	Radiation Safety Handbook for Ionizing & Nonionizing Radiation (GPO 017-015-00116-4, $1.70) (PB 262 109/AS, mf only).
FDA 77-8008	Imports - Radiation-Producing Electronic Products (GPO 017-015-00133-4, $0.70) (Revised August 1977).
FDA 77-8009	Comparison of Radiation Exposures from Panoramic Dental X-Ray Units (GPO 017-015-00122-9, $0.85) (PB 263 319/AS, mf only).
FDA 77-8010	Biological Effects of Electromagnetic Waves - Selected Papers of the USNC/URSI Annual Meeting - Volume I (GPO 017-015-00124-5, $6.50) (PB 268 094/AS, mf only).
FDA 77-8011	Biological Effects of Electromagnetic Waves - Selected Papers of the USNC/URSI Annual Meeting - Volume II (GPO 017-015-00125-3, $6.25) (PB 268 095/AS, mf only).
FDA 77-8013	The Mean Active Bone Marrow Dose to the Adult Population of the United States from Diagnostic Radiology (GPO 017-015-00119-9, $1.05) (PB 262 909/AS, mf only).
FDA 77-8014	Evaluation of MDH Model 1015 X-Ray Monitor (GPO 017-012-00241-2, $0.65) (PB 263 725/AS, mf only).
FDA 77-8015	Progress in Radiation Protection 1975.
FDA 77-8017	Nationwide Evaluation of X-Ray Trends: Organ Dose Index System - Radiographic Field Survey Procedures Handbook (GPO 017-015-00121-1, $0.80).
FDA 77-8018	Photographic Quality Assurance in Diagnostic Radiology, Nuclear Medicine, and Radiation Therapy. Volume II - Photographic Processing, Quality Assurance and The Evaluation of Photographic Materials (GPO 017-015-00123-7, $2.20) (PB 267 498/AS, mf only).
FDA 77-8020	Patient Exposure from Diagnostic X Rays: An Analysis of 1972-1974 NEXT Data (PB 267 741/AS, $4.00).
FDA 77-8021	8th Annual National Conference on Radiation Control: Radiation Benefits and Risks: Facts, Issues, and Options (GPO 017-015-00126-1, $5.50) (PB 267 317/AS, mf only).
FDA 77-8023	Radiological Health Training Resources - 1977 (supersedes FDA 75-8027).
FDA 77-8025	Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (GPO 017-015-00140-7, $2.20) (PB 272 303/AS, mf only).

BIBLIOGRAPHIC DATA SHEET	1. Report No. FDA/BRH-78/89	2.	3. Recipient's Accession No. PB283559

4. Title and Subtitle
9th Annual National Conference on Radiation Control - Meeting Today's Challenges

5. Report Date
April 1978

6.

7. Author(s)
n/a

8. Performing Organization Rept. No. FDA 78-8054

9. Performing Organization Name and Address
Department of Health, Education, and Welfare, PHS, Food and Drug Administration, Bureau of Radiological Health
5600 Fishers Lane, Rockville, Maryland 20857 (HFX-25)

10. Project/Task/Work Unit No.

11. Contract/Grant No.

12. Sponsoring Organization Name and Address
Cosponsors: Conference of Radiation Control Program Directors, Inc., Environmental Protection Agency -Office of Radiation Programs; U.S. Nuclear Regulatory Commission; and U.S.DHEW, PHS, FDA, Bureau of Radiological Health.

13. Type of Report & Period Covered Proceedings of Conference -6/19-23,1977

14.

15. Supplementary Notes

16. Abstracts

This publication contains the proceedings of the 9th Annual National Conference on Radiation Control - Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference of Radiation Control Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces are included in these proceedings.

17. Key Words and Document Analysis. 17a. Descriptors

Atomic Energy Act; BENT; CT scanning; genetically significant dose (GSD); laser; mammography; nonionizing; nuclear medicine; personnel dosimetry; quality assurance; radiation; risk factor; ultrasound; x ray.

17b. Identifiers/Open-Ended Terms

APPROVED FOR UNLIMITED RELEASE
William L. Jackson
WILLIAM L. JACKSON
DIRECTOR, FDA/PRDC (NTIS)
DATE 4/21/78

17c. COSATI Field/Group

18. Availability Statement Unlimited	19. Security Class (This Report) UNCLASSIFIED	21. No. of Pages 429
	20. Security Class (This Page) UNCLASSIFIED	22. Price A19-A01

FORM NTIS-35 (REV. 3-72)

THIS FORM MAY BE REPRODUCED

USCOMM-DC 14952-P72

HEW Publication (FDA) 78-8054

9th Annual
NATIONAL CONFERENCE ON RADIATION CONTROL

Meeting Today's Challenges

June 19-23, 1977
Seattle, Washington

April 1978

Cosponsored by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

•

ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation Programs

•

U.S. NUCLEAR REGULATORY COMMISSION

and

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland, 20857

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402

Stock No. 017-015-00148-2

ia

FOREWORD

The Bureau of Radiological Health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product radiation control program to protect the public health and safety.

The Bureau publishes its findings in appropriate scientific journals and technical report and note series prepared by Bureau divisions and offices. Under a memorandum of agreement between the World Health Organization and the Department of Health, Education, and Welfare, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

> WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations (Office of the Bureau Director)
>
> WHO Collaborating Center for Training and General Tasks in Radiation Medicine (Division of Training and Medical Applications)
>
> WHO Collaborating Center for Nuclear Medicine (Division of Radioactive Materials and Nuclear Medicine)

As a WHO Collaborating Center, the Bureau makes available its technical reports and notes to participating WHO members.

Bureau publications provide an effective mechanism for disseminating results of intramural and contractor projects. The publications are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, information services, industry, hospitals, laboratories, schools, the press, and other concerned individuals. These publications are for sale by the Government Printing Office and/or the National Technical Information Service.

Readers are encouraged to report errors or omissions to the Bureau. Your comments or requests for further information are also solicited.

John C Villforth

John C. Villforth
Director
Bureau of Radiological Health

CONTENTS

Page

FOREWORD. ii

ABSTRACT. ix

OPENING SESSION, SUNDAY, JUNE 19, 1977
Moderator: *Gerald S. Parker* 1

Welcome to the State of Washington
Lawrence B. Bradley. 2

Today's Radiation Protection Challenges
Margaret N. Maxey. 8

The Conference is Meeting Today's Challenges
Gerald S. Parker 15

Report on Federal Activities in Meeting Today's Challenges - Part I
William D. Rowe. 22

Report on Federal Activities in Meeting Today's Challenges - Part II
Robert C. Ryan 25

Report on Federal Activities in Meeting Today's Challenges - Part III
John C. Villforth. 27

SESSION: ISSUES IN MAMMOGRAPHY, MONDAY, JUNE 20, 1977
Moderator: *Gerald S. Parker* 33

Patient Reaction to the Mammography Controversy
Rose Kushner 34

Who Should Have Mammographic Examinations?
Richard G. Lester. 43

National Cancer Institute's Guidelines for Mammography
Winfred F. Malone. 51

Risk Factors to Consider in Surveying Asymptomatic Women
Albert W. Hilberg. 60

What Can and Needs To Be Done by State/Local Radiation Control Agencies
Alice Dolezal. 65

SESSION: WHERE DO WE STAND ON COMPUTERIZED AXIAL TOMOGRAPHIC SCANNING?
Moderator: *B. G. Brogdon*

CT Scanning's Place in Diagnostic Radiology
Ronald G. Evens. 69

Page

How Will CT Scanning Affect Patient Treatment and Care?
H. David Banta 74

Planning Aspects of CT Scanning
Patricia A. Gempel 80

Considerations in the Establishment of Performance Standards for Computerized Tomographic Scanners
Roger H. Schneider 91

State Radiation Control Concerns
Gerald S. Parker 103

GENERAL SESSION, TUESDAY, JUNE 21, 1977
Moderator: *B. Jim Porter* 115

Report of the National Bureau of Standards' Survey of State Measurement Needs
Elmer H. Eisenhower 117

TASK FORCE REPORTS SESSION
Moderator: *Alice Dolezal*

Evaluation and Distribution of Radioactive Sources and Devices Not Manufactured Under the Atomic Energy Act
Edgar D. Bailey 127

Criteria for Adequate Radiation Control Program
John W. Shaver 129

Nationwide Evaluation of X-Ray Trends
Beattie L. DeBord 139

Credentialing of Radiation Allied Health Operators
Donald R. Hughes 142

Suggested State Regulations
Charles P. Froom 151

Suggested State Regulations: Technical Review Committee
J. Dale McHard 156

Suggested State Regulations: Part C - Licensing of Radioactive Material
A. J. Hazle 158

Suggested State Regulations: Part K - Nuclear Pharmacy
Lynn A. FitzRandolph 161

Natural Radioactivity Contamination Problems
L. Hall Bohlinger 168

Radioactive Waste Management
Heyward G. Shealy 172

Establishment of Soil Contamination Limits
A. J. Hazle 173

Page

Public Health Impact of Nuclear Medicine Practice
Phil Brunner 174

Emergency Planning
Margaret A. Reilly 176

Notification Procedures for Radioactive Shipment
Leonard R. Solon 179

Quality Assurance
Chuck Hardin 180

Mammography
Henry J. Bicehouse 185

Radiation Measurements
Marshall Parrott 188

Personnel Dosimetry
Larry Lloyd 190

Report of the Working Group on the Leak Testing of the General License Devices of 10 CFR 31.5
A. J. Hazle 194

SESSION: X-RAY DATA AND GUIDANCE, WEDNESDAY, JUNE 22, 1977
Moderator: *Lawrence J. McDonnell* 203

Results of Repeated NEXT Surveys in the State of Oklahoma
Robert L. Craig and *David W. Johnson* 205

Potential Impacts of Control Program Efforts on Genetically Significant Dose (GSD) and Bone Marrow Doses
David W. Johnson 212

Breast Exposure: Nationwide Trends - Progress to Date
Ronald G. Jans and *Thomas R. Ohlhaber* 218

Federal Guidance for Diagnostic X Rays
James E. Martin 226

The States' View of Federal Guidance Report No. 9
David K. Lacker 228

SESSION: LOW-LEVEL RADIOACTIVE WASTE MANAGEMENT
Moderator: *William C. Horton*

NRC Task Force on Review of the Federal/State Program for the Regulation of Commercial Low-Level Radioactive Waste Burial Grounds
William P. Bishop, Michael J. Bell, Kitty S. Dragonette, and *John A. Adam* 230

State Experience with Waste Burial Sites and Their Response to NRC's Task Force
Frederick S. Adair, Charles M. Hardin, Heyward G. Shealy, and *James A. Blackburn* 240

Page

SESSION: SO YOU ARE GOING TO COURT
Moderator: *Donald E. Van Farowe*

Evidence Preparation
Raymond Malecko 251

Legal Aspects of a Regulatory Inspection and Enforcement Program
Allen D. Johnson. 255

Preparing to Act as a Witness
Richard A. Lane 259

SESSION: TECHNICAL POTPOURRI I
Moderator: *J. Ellis Simmons*

Use of Obstetric Ultrasound in U.S. Hospitals, 1974
Paul L. Roney and Peggy Hamilton. 262

Overview of Nonionizing Radiation Programs of NIOSH
G. E. Moss. 264

Problems at Inactive or Abandoned Fuel Cycle Facility Sites
W. T. Crow. 271

SESSION: NUCLEAR MEDICINE AND RADIATION THERAPY, THURSDAY, JUNE 23, 1977
Moderator: *Michael Christie*. 275

Regulatory Problems in Veterinary Nuclear Medicine
Dan Hightower, David M. Hood, and R. D. Neff. 278

Quality Assurance Workshops in Nuclear Medicine
Goldie Watkins and Richard J. Van Tuinen. 281

Cobalt-60 Teletherapy Survey
J. N. Gitlin and Donald L. Thompson 284

Status Report on Nuclear Pharmacy
Jerome A. Halperin. 287

SESSION: FALLOUT IN 1976
Moderator: *Edd Johnson*

Status Report on Thyroid Blocking Agents
Jerome A. Halperin. 290

Summary of Monitoring Results from State and Federal Programs
Floyd L. Galpin 293

Discussion of Federal and State Actions Related to 1976 Fallout Episode
Thomas M. Gerusky, John R. Stanton, and Floyd L. Galpin 304

Radioactive Contamination of Human Food and Animal Feeds - New Proposed Recommendations
Bernard Shleien, Floyd L. Galpin, John R. Stanton, and Sherwood Davies 312

Page

SESSION: NONIONIZING ACTIVITES
Moderator: *James C. Wynd*

Results of the EPA Environmental Radiofrequency Radiation Measurement Program
F. L. Galpin, T. W. Athey, N. N. Hankin, and D. E. Janes 317

Laser Light Shows - A New Challenge
Henry P. Copeland. 325

Control of Lasers in the Entertainment Field
Francis J. Bradley 330

Laser Standard and Related BRH Compliance Experience
Robert G. Britain. 337

SESSION: TECHNICAL POTPOURRI II
Moderator: *Eddie S. Fuente*

Status Report - NRC/EPA Task Force on Emergency Planning
Harold E. Collins. 342

Activities of the Atomic Industrial Forum of Interest to State Programs
E. David Harward 346

Spent Fuel Storage
T. Jerrell Carter. 355

PLENARY SESSION
Moderator: *David L. Lacker*

Use of Radiation in Benign Diseases
Albert W. Hilberg. 363

Thyroid Irradiation Followup Studies
Margaret H. Sloan. 369

Are State and Federal Agencies Meeting Today's Challenges? - Part I
Robert Alvarez 377

Are State and Federal Agencies Meeting Today's Challenges? - Part II
Terry R. Lash. 395

CLOSING SESSION
Moderator: *J. Dale McHard*

Report on Resolutions
J. Dale McHard 407

Executive Board Report
J. Dale McHard 408

Summation and Closing Remarks
Sheldon A. Schwartz, Robertson J. Augustine, James W. Miller, and J. Dale McHard 410

ABSTRACT

This publication contains the proceedings of the Ninth Annual National Conference on Radiation Control--Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference of Radiation Control Program Directors, Inc.; the Bureau of Radiological Health, FDA; the U.S. Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces and workshops are included in these proceedings.

Preceding page blank

The opinions and statements contained in this report are those of the authors and may not reflect the views of the Department of Health, Education, and Welfare (HEW), or necessarily represent the views or the stated policy of the World Health Organization (WHO). The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department or the World Health Organization.

OPENING SESSION

Moderator: *Gerald S. Parker*, Massachusetts

WELCOME TO THE STATE OF WASHINGTON
Lawrence B. Bradley, Office of Energy, State of Washington

TODAY'S RADIATION PROTECTION CHALLENGES
Margaret N. Maxey, Associate Professor of Bioethics, University of Detroit

THE CONFERENCE IS MEETING TODAY'S CHALLENGES
Gerald S. Parker, Chairman, Conference of Radiation Control Program Directors, Inc.

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES - PART I
William D. Rowe, Ph.D., Deputy Assistant Administrator for Radiation Programs, Environmental Protection Agency

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES - PART II
Robert C. Ryan, Director, Office of State Programs, U.S. Nuclear Regulatory Commission

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES - PART III
John C. Villforth, Director, Bureau of Radiological Health

WELCOME TO THE STATE OF WASHINGTON

Lawrence B. Bradley
Office of Energy
State of Washington

I am sorry that Governor Ray cannot be with you today and I know that she is too, but her commitments for personal family business got in the way. She sends you her greetings through me. She regards you as a kind of defense line of the nuclear business.

Washington was known for a good many years as "The Nuclear Progress State," and we carried this on our calling cards. I remember it was the only type of calling card of any State employee that had any kind of a slogan on it. It went undetected for a number of years until Governor Evans saw it one day and wanted to know how come we were in the advertising business. I merely told him where we were, at that time in the nuclear commitment sense, as far as the State went. I enumerated a few of the things that we had completed but, because of the way the office was originally structured in the Department of Commerce, we kept rather quiet, but for no good reason. It just was not the kind of an advertising thing to talk about. We just went about our business in a business sort of way and were able first to bring in a fuel fabrication plant.

As you know, it is in Richland; now known as Exxon Nuclear. The idea behind it was to have a full fuel cycle arrangement within the State of Washington, from our own uranium supply (it turns out to come from the Spokane Indian Reservation at a small plant that was built in Ford, Washington) that was processing the U-308. It was always my ambition and desire to see us as a self-sufficient State in an energy sense, since one of the things I was aware of when I came to the State government from the General Electric Company was that we were a net importer of energy, which may be a surprise to most of you who are visiting us from out of State.

It may be even a greater surprise to those of you who are residing in the State. We have been a net importer of energy for a number of years; for over 10 years. Our vast hydroelectric resource, which you see if you are driving along our rivers, has never been sufficient to do the whole job. The utilities have purchased energy for this State for the last 6 years that I know of. While it is a fact that our surplus energy has gone south, it was done on a reciprocity basis for energy that was supplied to us from the oil fueled plants in California.

Now, since oil is scarce and very high priced, we are witnessing a situation that nobody would have believed could have happened as recently as just 5 years ago. We are buying power generated at 50 mils per kilowatt hour, as it compares with the 4 mils that is sold to us from the hydroelectric resource. The result is that we have three of our largest cities now on a surchage basis. And that is an astounding thing in a State that has been energy conscious for so many years.

This is the second of your annual meetings that I have attended. The first one, I believe, was in Portland a few years ago when you were a much smaller number. I was delighted to be with you at that time because you were getting down to some nitty-gritty in those days in terms of the standards. These were being promulgated by the NRC, which was just coming aboard at that time. They were a holdover from the AEC standards that were being set for radiation exposure. As you remember, many of the requirements were not even measurable by any known instrumentation at that time.

Yes, they could be calculated, that was true, but we had witnessed, up to that point, a situation in Minnesota which was a most disconcerting thing to me and to Governor Evans. It happened where a local agency within the Minnesota government set upon to take the AEC standards and just jack them down 1,000 fold. That was passed at a public hearing attended by six people, which all of a sudden became a regulatory session. In Minnesota it resulted in a court suit, trying to test, then, the infallibility, if you will, of the AEC/State government desires.

We have become much more sophisticated now. The most recent occasion similar to that was in Colorado; the Colorado PIRG case. Now this is a situation where an organization in Colorado petitioned the State to set standards of its own rather than buy those standards that were set up by the NRC in terms of maximum radioactive effluent discharges. It might interest you to know the State of Washington joined Colorado in that suit because we are a State's Rights State, too. We would insist on our rights to set standards, and we will set standards as we want to.

And yet there are a lot of people within our own State belonging to some rather militant groups who do not believe we possess the mentality. They believe more, than anything else, in the cataclysmic. If you look at some of the records that we have set in the last 10 years, I think you will find that the State of Washington has been more or less the leaders in being prudent and circumspect all about the nuclear situation.

We have a problem, yes. All of us have a problem and that is a nuclear waste storage problem. That gets right to the heart and soul of what you people do and will be responsible for in the future. It's a mess, is the best way to sum it up. There has been a lot of shilly-shallying. A lot of failure to bite the bullet. A lot of starts in the right direction in terms of nuclear waste disposal sites. A lot of abortive attempts, a lot of poor planning by the Federal agencies; so badly done that one excellent site in Kansas is probably lost forevermore as a place to store high-level wastes. It was a salt bed, which is the most excellent way that . know of to store these wastes. Most of you, who are professional people in this business, will recognize what I am saying in terms of the dampening effect of radioactive emissions. That chance was lost in Kansas. I doubt very much whether it will be opened up again. But there is a move in terms of Carlsbad, New Mexico, as you know.

There are three matrices or possibilities for the burial of high-level wastes that will involve you people if any one of them is chosen and accepted in terms of a geographic location for such sites. Obviously, progress is being made toward another salt bed site and that would be Carlsbad, New Mexico to the greatest extent.

An announcement has been made and public hearings held already in the State of Washington in terms of a possible site here with burial planned in the basaltic formations possibly over in the Hanford area of Eastern Washington where the depths of basalt are already known to exist for 10,000 feet. They are absolutely impervious.

The other site, of course, is a granite matrix. And I think that that offers the least possibility; first of all because it is very difficult to get into and has a tendency to fissure. As for a basaltic formation, I was on the design team, designing underground burial possibilities. We came up with a vertical stovepipe with a telescope tripod, if you please--a standard design form with three legs. But the work has to be done by a mining company. We found a coal mining company with the only people who had the equipment and experience capable of drilling into basaltic formations.

The idea being that high-level wastes from the waste tanks, after the processing step was through, would be brought to the top of a vertical tunnel (stovepipe), go down in a car, automatically slide into one of the stopes (the tripod), and as that stope gradually filled up, it would be filled with concrete. And then the second one, and so on. Finally the top one, or the stovepipe.

It was cylindrical, obviously. Excavation ran to 15 feet in diameter as did the stopes out the side. Our calculations at that time, the high-level waste storage potential after the reprocessing step was over, the capacity of such a facility would take care of 10,000 light-water reactions. Can you image that? 1955; 20 years ago. All of a sudden it is a new thing.

So we are going back at the problem again. There are young people involved with it now. I am sure they are looking at it with probably the same eyes I did, and probably more acutely. We know a lot more today than we knew in 1955, but I will assure you we knew a lot then about radiation and how to control it. To that extent, the high-level waste situation, I think, will continue to plague us until the Government makes up its mind how it's going to be handled. And, in that connection, I am a member of a team made up from the Western Interstate Nuclear Board and shared by a similar organization called SINB, or Southern Interstate Nuclear Board. Both organizations have been pressing themselves with this question for about 5 years. We feel the time has come to fish or cut bait. There is no need horsing around any longer. There are many things happening in the nuclear business as far as power reactors are concerned that are very disconcerting to me personally because they are based on such falacious information as I have never seen before.

The latest force, I think, is probably in disguise; an avenue that may accelerate some decisions by the Federal government. My grapevine, which is a pretty good one in this State, tells me that there will be a move quite soon, probably by a referendum starting, of course, with initiatives to limit the amount of storage in situ for any given nuclear plant. What that quantity will be--I am told it will be probably something less than a full fuel core.

Most of you who understand the business know that that would probably take the best of about 5 years for the total core to be assembled on the site. After that, if there were no interim storage facilities, obviously the reactor would have to shut down and the public would be the losers.

Right now in Oregon at the Trojan site there is the right, by law I think, to store three sections of a spent core. They are now asking to increase storage to twice that. That's what sparked interest more than anything else. If you watch your newspapers in terms of the Trojan plant and the amount of spent fuel that is likely to be stored in situ, if there is a limit to be placed upon that, there is a lasting regulation. Of course, this is the means that the recalcitrants are taking to get around the moratorium laws that have failed so badly in each of our States. It is apparent that the principal need with the Federal high-level waste storage program is coordination of the multiagency programs that are involved. These individual programs are for the most part, I believe, quite sound, but each of them depends upon the success of the other. And that is always a problem with Federal agencies.

An independent coordinator is required to coordinate those related programs and to serve as a single point of contact for State governments. The coordinator should himself emphasize specific aspects that urge waste isolation pilot plant programs, such as Carlsbad, New Mexico.

What I just read to you is a joint policy statement up for approval between the WINB and the SINB. In a nutshell, and it is pretty clear; someone is needed very badly with the clout to bring the Federal agencies into line for an understanding of what this situation is all about so that one agency is not befouling another, in a sense, by issuing regulations that are in contrast or contradict one another. Most of you have experienced that already. I believe very sincerely in that one.

Washington also went into the low-level waste burial in which some of you are involved today. As you know, we have a low-level waste burial site at Hanford. I will take a minute or two to explain that for those of you who are from out of town and do not understand how this has happened. In 1966, a lease was entered into between the State of Washington and the Atomic Energy Commission for 1,000 acres of land with the right to sublease for nuclear related enterprises. The first lessee was the California Nuclear Company, which is now defunct. It was succeeded by the Nuclear Engineering Company, who is still our present lessee. At the present time we have around 350,000 cubic feet of low-level nuclear waste buried on our properties at Hanford. The site is very carefully policed, very carefully controlled, very carefully monitored, as are the shipments that come and go. The site has been in operation for some time. It was set up in the law--under the law of perpetuity, which for those of you with legal training know there is no such thing.

But I must say a perpetuity fund was set aside based on a fee per cubic foot of waste buried with a minimum amount of $20,000 to start. At the present time, with interest and all, we have got enough, if we had to get out of the site, probably to hire one crane operator and a crane. Such is the case with the escalation in labor and equipment costs.

Obviously, the State, if called upon to render the area back as it was before the burial all started, does not have the money to do such a thing. There is no difficulty with the site; there never has been. And since it has always been under my office, and now under the Office of Energy, I do not think there ever will be. We watch it very closely with the cooperation of Dr. Beare's people and Mrs. McClellan's people.

In some States there have been some difficulties, as you know--some handling slips by personnel, which, of course, are always the weakest link in this whole nuclear game of ours. So, low-level waste was dealt with. In that case, we came to the conclusion that under NUREG 0217 (that is kind of gobbledygook for government document issuances, nuclear regulations entered), the control of low-level waste disposal should be vested in the Federal government based on a testimony given by other Federal agencies to the Subcommittee on Energy and Environment in May of 1977. It is very recent. It is apparent that these agencies anticipate NRC to assume such control. I would say at this point the State of Washington, of course, would have no objections to that whatever. How much can you get done this day for 40,000 clams?

We have, then, prepared a letter that Dixy has not seen yet. I was hoping she was going to be here and I would have a chance to take care of it in front of all you people and then she probably could not say no.

I am not attempting to preempt her, since I will be with her tomorrow evening in Friday Harbor--we are in the town hall meeting mode these days. They have turned out to be quite successful and our next one is in Friday Harbor.

I would like to read the letter that we have prepared for her signature. Of course, it is a trial balloon and will be subject, I am sure, to some extensive changes. And in that connection, Mr. Adair from my office will be talking about the low-level waste situation. Those of you who are interested in that aspect in handling of low-level waste I am sure will be interested in attending that particular group of study courses. Mr. Adair will have a hand in getting this letter out in a crisp form and to the satisfaction of the Governor, as well as the governors of 29 states.

We hope to have a united front on this matter. So, let me take the time for just a second or two to read the letter from Dixy Lee Ray to President Carter.

> "I believe the status of nuclear power as a substantial element in our national energy supply is threatened by severe problems."

(I think that is the understatement of the year so we will change that right off the reel.)

> "Some of them are more illusionary than real, but their impact is no less powerful. Radioactive waste management is one of these problems and the problem area that has been particularly troublesome. I, together with the governors in 29 Southern and Western Interstate Contract States believe improvements are possible and needed in the Federal program for financing of management of commercial and high-level radioactive wastes."

(She doesn't, as you know, subscribe for 1 minute to the theory being advanced by some that the plutonium problem is as great as it is made out to be. So, she, like I, would agree highly that the most expensive way to get plutonium is to build a power reactor to produce it. That is absolutely absurd. There is plutonium from the defense program and that is more of a problem.)

"I offer herein specific recommendations to improve the Federal radioactive waste management program. We understand the current blueprints for Federal action to be delineated in the Resources Council presentation to the Joint Committee on Atomic Energy on May 10, 1976. We concur in the elements of this program, but believe that the management provisions are inadequate and that one element, the prototype waste isolation facility being developed at Carlsbad, New Mexico, should receive special attention. Management of the Energy Resources Council is by Committee.

"We believe that this is unworkable and that a single person of stature, ability, and technical knowledge, should be assigned to coordinate the whole program. In addition, this person would serve as a single point of contact for State government which is presently faced with contacting a myriad of Federal agencies to obtain information. And we so recommend."

(Obviously, that is a spinoff from the Washington State One-Stop Agency concept which is the way our Siting Council operates; 14 State agencies rolled into one Siting Council, and there is one decision to be made. That binds them all, and that binds every agency in the State. We have had that law since 1970.)

"Development of a prototype waste isolation facility is singled out as a program which can be understood easily by the public as proof that technology exists."

"Accordingly, preparation of the prototype facility should be accelerated and a small quantity of radioactive waste in solid form of spent fuel should be placed into storage as soon as possible. The origin of the waste, Federal or commercial reactors is unimportant.

"We also recommend with this step the recommended coordinators should assure that the overall multi-agency program proceeds on schedule and should focus agency management attention where needed. Also, he would single out the Carlsbad facility and identify specific target dates that would put that facility into service as a development facility at the earliest possible date, and then publicize those dates, characterizing the Carlsbad development as a viable, ongoing program, and take special care to see that the target dates are all met. In addition, he would serve as a single point of contact for all state government.

"We believe adoption of the above recommendations will improve the Federal radiation management program and will raise public confidence in nuclear power. And we therefore strongly urge your favorable consideration of these recommendations. Very sincerely yours, Dixy Lee Ray."

Now, obviously, that is the crux of the problem. There are nine Federal agencies involved in the waste management program. None of them seem to coordinate their interests with the other. In fact, they are not interested in that.

When we talk to them, from the State's standpoint, it is like going to a bunch of strangers. Regulations differ between the Federal agencies and that cannot go on. Each one now is taking a different look at the overall program and the spectrum seems to be running from, "Let's stop it all," as evidenced in President Carter's Energy Message to, "Let's not proliferate, but let's sophisticate what we've got, and thus take care of all of the problems being raised by the recalcitrants."

We, obviously, in Washington are out in the forefront of all these things. We have 7,000 megawatts of nuclear power certified in this State of which 3,000 megawatts is under construction at this time. The other 4,000 are involved in the Satsop plant which, in a sense, is under construction because ground breaking has taken place, and the Skagit Plant to the north of us here. Each plant being capable of producing a little bit in excess of 2,000 megawatts of power.

I believe that this State has produced a record. It is absolutely unassailable technically or legally. So far it has withstood every test that has been put to it. So, we have a definite reason and desire to see something in the waste management program getting underway at the earliest instant. We have done our work. Now the Federal government, who originated all this, has to do theirs.

TODAY'S RADIATION PROTECTION CHALLENGES

Margaret N. Maxey
Associate Professor of Bioethics
University of Detroit

As I have prepared to face the challenge of addressing my thoughts to the subject you have given me--radiation protection--I have discovered many reasons to affirm this time-honored truism: "Philosophy always buries its undertakers."

More often than not, we tend to confront the problems of our age as if they are unique and unprecedented, fraught with novel, unforeseen, insuperable dangers. We tend to carve them out for special treatment, as if no method of thinking about them and of working out solutions to them has existed heretofore. If ever a problem has captured our collective fears from the past, and held us hostage to the future, it is the invisible biohazards associated with ionizing radiation. Such diverse disciplines as biology, biomedicine, economics, political science, sociology, and psychology have been martialed to cope with the presumed hazards of radiation sources--whether medical, industrial, or cosmic. After decades of painstaking research into the somatic and genetic effects of radiation, the pressure of events seems to have compelled a number of scientists to review and reexamine the evolution of what they refer to as a "radiation protection philosophy." What intrigues me about the concept of a "philosophy" of radiation protection is not so much the way it is spelled out for examination, but rather the habit of mind that it reveals.

After all the statistical studies and projected extrapolations and regulatory hearings are said and done, even the most scientific mind is compelled to confront these fundamental philosophical questions: namely, To what purpose? With what criteria...? For whose benefit or harm...? What is safety? How safe is "safe enough?" In other words, philosophy is alive and well and challenging us with the same questions humankind has wrestled with throughout history. The "unprecedented problems" may appear to change, but the questions about them do not.

Just a year ago, Dr. J. N. Stannard (Prof. Emeritus of Radiation Biology and Biophysics at the University of Rochester Medical Center) undertook a review of the general philosophy used over the years in the development of radiation protection standards (1). Prior to the midfifties, recommendations were concerned almost exclusively with occupational exposure, with avoiding unacceptable biological injury to individuals. But when fallout from atmospheric testing of nuclear weapons in the midfifties introduced the possibility of population exposures, several scientific committees (U.S. National Academy of Sciences, the British Medical Research Council) suggested quantitative limits couched in terms of "significant doses" having "integrated effects" per million of population. By the early 1970's, increasing knowledge acquired from radiobiology prompted both the NCRP and the ICRP to recommend individual dose limits (500 mrem/year) and average population dose limits (170 mrem/person/year) on the basis of both genetic and somatic considerations.

These early phases in the development of radiation protection philosophy, says Dr. Stannard, were dominated by biomedical considerations regarding the acceptability of effects upon different organs having different radiosensitivity (e.g., the "critical organ hypothesis") and differences in types of radiation (e.g., a "dose-modifying factor" or "quality factor"). Subsequently, however, this focus on biomedical effects has been profoundly modified, if not displaced, by two factors: (1) the use of cost-benefit analysis; and (2) the application of a linear no-threshold hypothesis to developing standards that purport to keep radiation exposures, measured in person-rems, "as low as practicable" (ALAP) or "as low as readily (reasonably) achievable" (ALARA).

What accounts for these modifications? One major explanation, offered by Dr. Stannard, seems to be the pressure to prepare Environmental Statements to meet NEPA requirements. On the one hand, the pressure to generate risk-estimators has resulted in oversimplifying complex and disparate biomedical information. On the other hand, the need to estimate costs of eliminating adverse health effects has resulted in another oversimplification--namely, "a simple linear correlation between reduction of health effects and cost per unit of reduction."

The upshot of all this, laments Dr. Stannard, is that the precepts of radiation protection philosophy have been distorted by an emphasis on balancing health costs with societal or economic benefits. This overemphasis has had two unwarranted, if not dangerous, consequences. One is that technological possibility or feasibility and cost-effectiveness have all but eclipsed consideration of demonstrable, identifiable biological effects which the radiation standards set by regulatory agencies are intended to safeguard. A second consequence is that regulations that fail to balance all the factors involved mean that regulators are not engaged in radiation protection but rather "an exercise in finding the maximal cost" that a profession or a process or an industry can tolerate. In too many cases, the term "readily achievable" has been interpreted to mean, "If you can do it technically, you must do it" without regard to excessive effort or cost. The upper limit of 25 millirems could just as well be 75 or 100 or more without any greater probability of increasing demonstrable health effects.

Fortunately, it is not my appointed task on this occasion to pass judgment on Dr. Stannard's review of radiation protection philosophies. However, his review does open a window through which today's challenges might be seen more clearly. Of the three which I have selected to call to your attention, the one I consider most urgent has emerged from what is popularly called "the environmental crisis," "our crisis of finitude," or "man's discovery of an ecological conscience."

I. FIRST CHALLENGE: RADIATION CONTROL IN A CULTURAL CLIMATE OF CRISIS

Without a doubt, we are the best informed society in history. Consequently we are the most forewarned, anxiety-prone, exhorted, and guilt-ridden of cultures. For three reasons, this state of affairs is novel:

(1) dire predictions are being made, not simply by run-of-the-mill alarmists, but by several "authorities" or "experts" who appear credible;

(2) their projected catastrophes are not local or national but global; and

(3) their credibility is enhanced by the dramatic medium of mass communication, and the public's insatiable thirst for bad news.

At least since Earth Day 1970, we have been inundated with allegedly hard evidence that the deterioration of the human species and our natural environment is accelerating at an exponential rate, and that our only habitable planet has been raped and polluted by technological man, recklessly driven on by rugged individualism and selfish greed (2). The damage inflicted seems gargantuan. Rivers and streams have been turned into sewers: Lake Erie is dead and Lake Michigan is fast dying. Species of birds and animals are becoming extinct at a rapidly increasing rate: the last dodo died in 1689, with hundreds of other species dying since. Our insecticides and weed poisons may have increased food supplies for an exponentially increasing population, but these toxic chemicals appear to have found their way up the food chain to enter and poison ourselves. The "green revolution" in underdeveloped countries seems to have had disastrous unforeseen consequences: soil depletion, followed by erosion and floods, plus the food that has helped to sustain an upward spiral of already vast and starving populations. More people to feed, clothe, and shelter means a greater consumption of energy and an eventual exhaustion of nonrenewable resources. The nuclear reactors already in existence have produced radioactive wastes that will remain hazardous for a quarter of a million years--not to mention the hazards from mining and mill tailings.

Technological interventions, pretending to be "solutions," are indicted for being not only insufficient but downright dangerous: it is advanced technology in industry, agriculture, and medicine that has generated the environmental crisis in the first place. Our high-technology society is accused of having done more than any other to release toxic chemicals and radiation sources into our environment. Allegedly, radioactive carcinogens have made preparing food a lethal operation. Expert environmentalists now tell us that even mother's milk is poisoned. The world has become dismally unsafe.

Permit me to suggest that this environmental-crisis-mentality--plus the social movement, the Federal legislation of 1969 (NEPA), and regulatory machinery generated by it--constitute the first challenge that needs to be met: namely, how are we to recover and maintain a historical perspective on the alleged hazards posed by radiation sources in the present cultural climate of crisis? There are many who insist that the dangers posed have generated a self-evident crisis. But no crisis is self-evident. There are only recognized problems which have, in some people's minds, assumed critical importance.

Has manmade radiation caused the world to become dismally unsafe? What does the historical record show?

Those who express a profound aesthetic disgust for "technological pollution" and express a nostalgic wish to return to the simpler, purer life of a hundred years ago--free from the technological advances which have caused environmental degradation--would profit from a reading of Otto Bettman's book, "The Good Old Days--They Were Terrible" (3). As we condemn Detroit and auto emissions for making city air unbreathable, let us not forget a New York in 1900 with 150,000 horses in the street and the emissions they produced. Let us recall the local waste-management accepted as standard procedure: kitchen slops, cinders, coal soot, and other trash piled high on city sidewalks. When the younger generation tells us that our air and rivers would be clean and potable if only they had not been befouled by profit-seeking corporate industralism, some pages from history need to be re-read. Past civilizations have handled human wastes with such primitive sewage-practices that water pollution was worse than it is today in many places. During our entire lifespan on earth, the quantity of air pollution produced by mankind does not begin to equal the quantities of gases and particulates spewed forth into the atmosphere from just three volcanic eruptions: Krakatau in Idonesia in 1883; Mt. Katmai in Alaska in 1912; and Hekla in Iceland in 1947. Mother Nature releases 10 times more carbon monoxide into the atmosphere than all the activities of man.

When consumer advocates go through their litany of technology-induced hazards in the biosphere--citing in particular excessive radiation-therapy, pesticidal chemicals, carcinogenic food additives--we should restore some historical perspective to the mounting crescendos of fearful protest. Among others, William Lowrance (4) reminds us of what a life without advanced technology applied to medical care, to agriculture, and to generating electricity was really like: spoiled food, impure water, boiling laundry kettles, and the backyard lye pot. The major insecticide 75 years ago--sprayed on everything from apples to strawberries to grapes--was lead arsenate or "Paris green." Women canned food with such preservatives as boric acid and formaldehyde in high concentrations. Red food coloring was not red dye #2, but lead chromate--a horror to today's biochemist. Fatal diseases were not leukemia or Hodgkins disease or subtle forms of cancer; they were pneumonia, influenza, and tuberculosis. The average life expectancy at the turn of the century was 45 years. More than 13 percent of all infants died before their first birthday. The leading antiseptic in homes and hospitals was corrosive carbolic acid. Today, as we worry about the disinfectant hexachlorophene in soap, why do we so easily forget the harsh carbolic acid it has replaced, and the surgical operations it has made safer?

Certain persons like to identify themselves as technological pessimists, victims of "high technology" rather than beneficiaries, paranoid about the hazards which "experts" are introducing into their environment. They may believe that they are suffering from a "loss of confidence" in scientific expertise. In fact, they are suffering from a severe case of historical amnesia and cross-cultural blindness.

A new Quality of Life Index (PQLI) devised by the Overseas Development Council uses three criteria to measure how well nations are meeting basic necessities for food, sanitation, medical care, and education. These are (1) life expectancy, (2) infant mortality, and (c) literacy. Those nations which rank highest on this index (Sweden = 100; United States = 97; USSR = 94) are all technologically advanced. China (59), Algeria (42), and India (39) rank lowest among those measured on the PQLI index.

Has our world become "dismally unsafe" because of advances in scientific research and technology? Have environmental hazards increased in fact, or only in our levels of perception? Lowrance puts the case well:

> "We now have the luxury to worry about subtle hazards which at one time, even if detected, would have been given only low priority beside the much greater hazards of the day."

I am not for a moment suggesting that we should abandon attempts to control or reduce manmade, technology-induced radiation sources in our environment. But I am suggesting strongly that those responsible for radiation protection standards must meet ethical priorities for maximizing public health for the many--that is to say, the working class, the poor, the elderly, the vulnerable persons in our society--and not the vocal minority. Let us not lose sight of the fact that the ecology movement flourishes only in affluent nations, and only among groups of persons whose socioeconomic level and quality of life have guaranteed that basic subsistence and security needs have been abundantly met. When the more articulate and powerful middle classes pressure government agencies to remedy certain features in the environment, let us ask an important question: do these priorities reflect the concerns of blue-collar workers and the poor and elderly? --or do they represent a narrow set of private judgments about public priorities, based on the concerns of a rather well-off leisured minority? Environmentalists' priorities do not necessarily, much less by definition, coincide with ethical priorities.

II. SECOND CHALLENGE: THE USES AND ABUSES OF COST/BENEFIT/RISK ASSESSMENTS

The need for establishing ethical priorities about radiation control programs leads me to suggest a second challenge. Namely, how to evaluate the uses and abuses, the limitations yet necessity, of making cost/benefit/risk assessments as a condition for setting priorities in public health protection? The BEIR Committee has recognized the possibility that cost/benefit assessments, if truncated or inadequately conducted, might single out some biohazards for regulation, and in so doing, actually set up conditions for a decrease in public health. Their admonition is stated in this way:

> "...the public must be protected from radiation but not to the extent that the degree of protection provided results in the substitution of a worse hazard for the radiation avoided.
>
> "Additionally, there should not be attempted the reduction of small risks even further at the cost of large sums of money, which spent otherwise, would clearly produce greater benefit" (5).

There are at least two cases in which a Federal regulatory agency, the EPA, seems to have disregarded this caution when applying great zeal to implement the upper limit, zero-threshold, linear-dose model which the BEIR report proposes simply as a recommendation.

Consider the case of radium which is present wherever natural uranium occurs in the earth's crust, and may be carried off in surrounding water. According to studies in Argonne National Laboratory, persons exposed to such water at various locations in this country have exhibited what is called "a significant retention of radium." In its 1976 survey, the EPA discovered that some 500 U.S. community water systems "exceed a level of 5 millionths of a microcurie of radium-226 per liter." Accordingly, it promulgated a ruling in July of last year that all water systems would have to be monitored for radium, and those having more than 5 picocuries (i.e., a millionth of a microcurie) per liter would have to remove the radium by chemical means. Such radium removal will cost some $10 million according to EPA estimates. The reduction in radium exposure is expected to save almost four lives per year (6).

Is this a case of properly conducted cost/benefit/risk assessment in setting ethical priorities? I do not think so. Some regulator has judged that naturally occurring radiation in drinking water, measured in a millionth of a microcurie, constitutes an unacceptable biological hazard to public health. But is the applied risk assessment consistent? If a Federal regulation requires certain communities to spend over $2 million to save one life from exposure to radiation risk, should not the EPA be consistent and compel medical facilities in every American community to spend far greater sums of money to eliminate excessive exposure to diagnostic x rays and radiopharmaceuticals? According to one estimate, medical x rays exact a cancer toll of 2,700 deaths per year (6).

A second case in point concerns the EPA regulation to be imposed on the uranium fuel cycle which requires that it contribute nothing in excess of 25 mrem/year to the exposure of any member of the public. It has often been pointed out that this regulation is much more stringent than radiation levels ignored, or at least tolerated, in several other technology-induced sources. The 25 mrem ceiling per year is:

> "A factor of 20 less than the 500 millirem per year measured in the Grand Central Station in New York City;
>
> a factor of 20 less than the 500 milliren per year of cosmic radiation received by an airline stewardess who spends 20 hours per week at high altitude;
>
> a factor of 4 less than the 100 millirem geographical difference in natural background radiation between Denver, Colorado and New Haven, Connecticut;
>
> a factor of more than 1,000 below the lowest dose rate at which any harmful effects have been observed on either people or test animals" (7).

Clearly, the challenge illustrated by these cases is to find a more responsible institutional and/or social process for utilizing risk assessments, and cost/benefit analyses, in such a way that they will maximize the effectiveness of regulations in their only justifiable intent--to protect the public health of the many. Surely it is an obvious ethical imperative that government agencies should avoid targeting for regulation only those communities or technologies that are tractable, or easily accessible to control, or defenseless against the powers of government agencies and career intervenors using the courts to enforce prohibitive costs on a community or enterprise.

III. THIRD CHALLENGE: REGULATORY AGENCIES AND PUBLIC MISCONCEPTIONS OF SAFETY

The third and final challenge I want to call to your attention emerges from the very concept of governmental regulatory agencies as they have resulted from, and been sustained by, public misconceptions about safety.

One of our most pressing social issues is the so-called "crisis of public confidence" in professional experts. The more arcane and complex a scientific or technological development becomes, the more constrained is the "plain man" to fortify himself against erosions of his own level of understanding and his familiar world. Unable to stop the world and get off, he has little recourse except to demand that "the government" control or stop the whole process by multiplying regulators and regulations. I submit that the crisis is not generated by professional incompetence of experts, but by the social mechanism for enforcing rules and regulations through which that expert testimony is forced to pass.

Persons with far greater wisdom than any I possess are convinced, from the record of the last hundred years, that the system of regulatory agencies is inherently deficient. Problems are fragmented, proliferated, and the current of accountability gets passed along only one way: downstream. Costs for regulatory controls are externalized and passed on to angry taxpayers. Enforcement of regulations has to be turned over to the judicial system with interminable, irreversible, costly delays. The best intentions in the world eventually come to grief in a creeping Parkinsonianism. Frustrations within the system are mobilized into empire-building.

Why has the system of regulatory agencies been tolerated for so long, despite its glaring intrinsic deficiencies? The major reason seems to be that the public has labored under a profound misconception--never more apparent than in the debate over the disputed safety of nuclear reactors and radioactive-waste-management options. The "plain man" thinks (or is led to believe) that "safety" is an intrinsic, unconditional, measurable property that some system or product can and should possess. Consequently, the regulator is appointed and paid to measure approximations to that mythical property. It is the business of the watchdog regulator to make ever-more-stringent regulations, presumably to come ever-closer to that property by "reducing risks." But the only risks he is expected to monitor and minimize are a small percentage of the total risks tolerated by members of the general public. His job is not to be reasonable or to worry about the social and economic impacts of his ever-changing regulations. Just what value judgment does a regulator use when he demands more and more costly levels of safety? Is he "only giving the public what it wants?" Not at all. To paraphrase Tobias Burnett (8), a regulator can no more admit that what he regulates is "safe" than any other professional can admit that his job is finished and he has become unnecessary. No matter how minor a risk is, it can always be reduced. There is no number that cannot be divided by 10.

Evidently, the public has yet to realize that safety is not an intrinsic property, measured by approaching zero-risks. It is a relativistic, subjective, evolving, shifting judgment based on one's current value-priorities. It can never divest itself of risks. It can only judge their acceptability. There are as many judgments of "safety" as there are people and priorities.

The challenge confronting the regulatory system, as presently constituted, is formidable: Some social process must be instituted that will compel the public to reach a consensus on an ultimate question--just how much safety are we willing and able to pay for? Any human life is of infinite value only in abstract theory or religious piety. If we are to avoid compounding socially destructive policy decisions made by regulatory agencies which are in conflict with the common good of the many, the public must be educated to deal with the costs of safety. Zero-risk and absolute safety are indeed costly illusions. Fortunately, man does not live by "safety" alone. The challenge is to rediscover what else we live by.

REFERENCES

1. Stannard, J. N. "Statement for Hearings on EPA Draft Environmental Statement on Environmental Radiation Requirements for Naval Operations of Activities in the Uranium Fuel Cycle" and Supplementary Information on Proposed Standards. Washington, D. C. March 8-9, 1976.

2. For example: Paul Ehrlich, The Population Bomb (New York: Ballantine, 1968) George Borgstrom, The Hungry Planet (New York: Macmillan, 1965). John Cobb, Is It Too Late? (Beverly Hills: Bruce, 1972). Barry Commoner, The Closing Circle (New York: Knopf, 1971).

3. Bettmann, Otto L. The Good Old Days--They Were Terrible! (New York: Random House, 1974).

4. Lowrance, William. Of Acceptable Risk (Palo Alto, Ca.: William Kaufman, 1976).

5. BEIR, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," Advisory Committee on the Biological Effects of Ionizing Radiation, National Academy of Sciences - National Research Council, Washington, D. C., p. 2.

6. Lapp, Ralph. Radioactive Waste--Society's Problem Child. Reddy Communications, Greenwich, Conn., 1977.

7. Burnett, Tobias. "Environmental Radiation Protection for Nuclear Power Operations; Proposed 40 CFR 190," Testimony before the Hearing Board of the EPA, March 9, 1976, pp. 2-3.

8. Burnett, Tobias. "The Human Cost of Regulatory Delays," Nuclear Technology, April 1977.

THE CONFERENCE IS MEETING TODAY'S CHALLENGES

Gerald S. Parker
Chairman
Conference of Radiation Control Program Directors, Inc.

The Conference of Radiation Control Program Directors would like to thank Bob Will and his staff for hosting the Ninth National Conference on Radiation Control. The Conference also thanks Dave Flora of FDA and Ed Cowan of EPA for all their help in arranging this meeting.

During the past year, we have strengthened our relationship with the three sponsoring Federal agencies (BRH, EPA, and NRC) and our fourth collaborator, NBS. I believe that it is beginning to be a true partnership. When the Conference first started, it was too often a one-way street from the Federal agencies to the States. I believe the Federal agencies now realize that for a true partnership there has to be a two-way relationship. The Federal agencies also began to realize during this past year that they have something that most States do not have--that is, "time." For those of us on the firing line, we do not have the luxury of studying a problem for several years. We have to take some sort of action based on the information that we have available. I believe that we must and will have the cooperation of the Federal agencies in solving some of our problems in a more timely fashion. However, to attain that goal, we must have the cooperation of each and every member of the Conference and of its Task Forces. As I said last year to the members, "Ask not what the Conference can do for you, ask what you can do for the Conference."

In order to meet the challenges in a timely manner in the healing arts area, the Conference established a Healing Arts Council. The Healing Arts Council was established in order to deal with Healing Arts radiation control matters in a more expeditious manner. The Council serves as a vehicle of communication between the Board, the Task Forces, and the Federal agencies and is able to respond more quickly to any problems that may arise. The Council also evaluates the programs of the Task Forces and provides the Task Forces with Guidance. The Council has proven to be a worthwhile idea and, consequently, the Board is considering establishing the same type of council for the environmental area.

You may recall that I said that something had to be done about Emergency Planning during the past year. I am sure that you are aware that something has been done. Members of the Task Force on Emergency Planning met with NRC personnel to see if it would be possible to reduce the number of items States would have to do in order to gain concurrence. The Guide checklist was shortened and so the burden is not as weighty as it was 1 year ago. However, in spite of the fact that it has been shortened, it is still too much of a burden for most State radiation control programs to be in compliance with WASH 1293 or NuReg 75/111. The NRC will be reviewing this checklist at least yearly and it is hoped that the checklist can be shortened even further. The Task Force, under the able leadership of Margaret Reilly, will be working with NRC during the coming year to meet this challenge of a guide and checklist that is acceptable both to the States and to NRC.

Another challenge emerged as a result of the Medical Devices Act. When the Bureau of Medical Devices personnel began visiting each of the regions, it became apparent that there was no clear policy on what should be done about those devices that already were regulated either by the States or other Federal agencies. Especially worrisome to some was the possibility that the Bureau of Medical Devices would preempt State Radiation Control Programs. Again it was a question of time. The States did not want to take a chance of their programs being preempted. Consequently, a number of States filed petitions for exemptions from the Medical Devices Act that related to radiation control program activities. I am happy to be able to report that as a result of discussions between the Executive Board and FDA personnel, as well as the petitions mentioned above, the States have been given assurances that there is no intent to preempt the regulatory activities of the States' radiation control programs. California, which has a separate Medical Devices Act, is pursuing the exemption route. The hearing is scheduled during the month of July.

Another area of concern during the year was Transportation of Radioactive Materials. The Conference appointed four members to serve on a Task Force in a study being conducted by Sandia Corporation under an NRC contract. Sandia was to develop an environmental assessment model to estimate the effects of the transportation of radioactive materials near and through high-density population areas. The Conference members have found this Task Force to be a worthwhile one and very educational. However, it is not answering some of the questions that are bothering us. Who should receive notification? How should this notification be given? Who should designate the routes that the transporter shall use while passing through the States? The Task Force Chairman, Len Solon of New York City, has recommended that the Conference should have its own Transportation Task Force. This will be done during the coming year.

The challenge of mammography kept rearing its head during the past year. The question of who is to be mammographed has not been an easy one to answer. When this question was first raised several years ago by John Baillor, he was dismissed as a misguided individual by many of his colleagues. As everyone knew at that time, mammography was detecting disease earlier and patients' lives were being saved, or so the HIP study told us. Now, several years later, it seems that mammography was oversold and maybe those who questioned the ACS-NCI 27 center proposal were correct. It seems that the HIP study did not answer all the questions that it was supposed to. It would appear that we had a disease called "Mammography Fever" during that period when the practitioners, whether they could interpret images or not, were rushing to purchase mammographic units and to write about the accomplishments of mammography. This is not unlike the disease called "CAT Fever," as described by Shapiro and Wyman. Too often we dismiss the questions raised regarding generally accepted practices without fully investigating the issues that they are raising. The emotional attacks on the people raising the questions are dangerous because they keep us from dealing with our problems in a scientific manner. Hopefully, we will not make the same mistakes in other areas of radiology that we made with mammography. This unmet challenge of determining who should undergo the various therapeutic and diagnostic procedures in radiology should be met by the radiation control people and by our colleagues in the battle to save a rad--the radiologists. I will have more to say on this question in a few minutes. The Conference's Mammography Task Force met several times during the year and participated in the symposium on the physics of mammography. This Task Force is presenting some recommendations on what can be done to ensure that there is proper quality assurance in the mammographer's office. BRH's BENT program is helping us come up with the data to make these recommendations. It is clear that effective guidelines are needed in the design, manufacture, and selection of x-ray equipment and image receptor systems.

The advent of computerized tomography a few years ago has given rise to questions about what is being done in all areas of radiology. Although we are attempting to find answers concerning CT at many levels, we have never asked the same questions about routine radiography, cerebral angiograms, pneumoencephalograms, and radionuclide brain scans. As an example, what effect do any of the above procedures have on the course of treatment that a patient receives, or on patient outcome? What clinical symptoms should a patient have before any of these procedures are conducted? Although we continually stress the importance of the design of equipment and the training of personnel for the reduction of individual radiation exposure, seldom is anything said about reducing the number of procedures involving sources of radiation in order to reduce average radiation exposure.

The elimination of unneeded tests may contribute more to the reduction of average radiation exposure than properly designed equipment and training. Professor White of The Johns Hopkins University said in his testimony before Congress, "But if the scanner makes no difference to the outcome of brain injuries, this should raise questions about the value of the previous diagnostic procedures. If neither contributes to improved outcome, why subject the patient to them and why allocate new resources to procedures that appear to make little difference." The time has come when we must answer the question, "Who should undergo the various diagnostic and therapeutic procedures that involve sources of radiation?" The recent Institute of Medicine CT study states that CT scanning of the head is not an appropriate diagnostic procedure in the absence of strong clinical indications and supporting signs and symptoms. Should we, the radiation control people, and the radiologists not require the same for all other procedures? A reduction in the number of procedures will not only cause a reduction in overall radiation exposure, but it will also have an effect on cost control. The name of the game in Washington and in the States is cost control. I believe that both the radiation control people and the radiologists must meet the challenge of reducing costs and radiation exposure. Although the time for this to occur has arrived, this will be a difficult task. As Archibald MacLeish said, "There has been much repetition of a saying...to the effect that nothing can stand in the way of a cause whose time has come. It is an impressive, almost Orphic, remark which has only one defect: that it isn't true. Almost anything can stand in the way of a cause whose time has come, and the later the time the greater the crowd: habits of mind, entrenched opinions, vested prejudices...The truth is, of course, that causes do not achieve themselves, however ripe their time. Causes are achieved by men and women."

The Quality Assurance Task Force has defined QA as those activities that can be implemented to result in a reduction of radiation exposure to the patient and/or improvement in the quality of the radiograph. They should also study what reduction of radiation exposure will occur by requiring physicians to request the radiologist to do certain procedures only after the presence of strong clinical indications and supporting signs and symptoms are detected in a patient. If the radiologists and radiation control people can meet this challenge, we collectively will have contributed a great deal to the welfare of the patients and the country.

One of the hardest challenges the Conference met during the past year was the completion of the first NARM Guides. The Conference has accepted the report of the NARM Task Force and while we are in Seattle, we will be meeting with the Federal agencies regarding the publication of the guides. This was not an easy challenge, but it has been met. Within a few months, each of the States will have guidelines for the evaluation of NARM products. Not only will it be helpful to the States, it will be also helpful to the manufacturers of NARM devices. However, the challenge of what to do with environmental NARM products has not been met. During this meeting, the NARM and Natural Radioactivity Contamination Problems Task Force will be meeting to initiate the process of addressing the above challenge. I believe that this challenge will be met during the coming year.

The Task Force on Natural Radioactivity Contamination Problems has submitted a 101-page report. They have met the challenge of determining what the States and Federal agencies should do about controlling the effects of the processing of naturally occuring radioactive materials and controlling the effects of natural radioactivity in the environment. Tomorrow you will receive a detailed report from this Task Force. The challenge to both the Federal and State agencies now is to take action in a timely fashion to implement the 19 recommendations contained in their report.

The Task Force on Radiation Measurements has determined what has to be done to attain reproducibility of radiation measurements. A great deal of cooperation between the States and all Federal agencies will be needed to achieve this goal. Hopefully, this cooperation will be forthcoming during the coming year so that this challenge can be met.

Resolutions

Last year, at the Eighth Annual Conference, two resolutions were passed; and during August of 1976, after polling the membership, an additional two resolutions were passed. Resolution 1 reads:

"WHEREAS regulations are constantly under revision;

"WHEREAS there is a tendency to perpetually add to regulations;

"WHEREAS seldom is any authorization which no longer having beneficial use removed from regulations;

"WHEREAS regulations must be continually justified to those being regulated and the general public; and

"WHEREAS a specific license can be used for those exceptional situations where the use is justified on a case-by-case basis: therefore,

"BE IT RESOLVED that the Conference petition the NRC to review its current regulations and purge those portions of the regulations not in step with present day radiation protection philosophy.

"(Two examples of the need for review are the general license of source material to physicians and pharmacists, and the Exemption from Licensing of scandium-46 for well logging.)"

NRC has made a deliberate effort to review and update the regulations that were carried over from the Atomic Energy Commission. Priority consideration was assigned to those areas of the regulations having the greatest potential impact on the nuclear regulatory process and the protection of public health, safety, and the environment. When the high priority re-evaluations are completed, attention will be given to a general purging of outdated provisions. The two specific regulations mentioned in the resolution--the general license of source material for physicians and pharmacists, and the exemption of scadium-46 for well logging--because of their rare usage, do not appear to warrant priority attention and, therefore, are not expected to undergo review, and likely elimination, until next year. NRC has requested that the Conference inform them if the retention of these regulations in the interim is presenting problems. This will be discussed at the Business Meeting and NRC will be informed of the decision of the members of the Conference.

Resolution 2 reads:

"WHEREAS the technical assistance activities of the Environmental Protection Agency, including analytical laboratory support and radiation monitoring has been of immeasurable help to radiation control programs of the States, thereby benefitting the public health of the Nation; and

"WHEREAS the Environmental Protection Agency has been directed to reduce or eliminate the provision of such a system to the States:

"BE IT THEREFORE RESOLVED that the President and Congress of the United States be made aware of the concern of the Directors of State radiation control programs in the loss of such technical assistance and that the President and Congress be encouraged to make every effort to restore and perhaps increase this important and necessary function of the Environmental Protection Agency as one means to insure the continued protection of the Nation's public health and safety through cooperative State/Federal radiation control programs."

As I am sure you are aware, this budget item was restored to the Environmental Protection Agency.

Resolution 1, that was passed in August of 1976, reads:

"WHEREAS, the continuous improvement of nuclear medicine scintigraphic instrumentation will yield high quality diagnostic images;

"WHEREAS, such images are essential to the evaluation and clinical management of nuclear medicine patients;

"WHEREAS, it should be the goal of all nuclear medicine departments to maintain a high level of diagnostic accuracy in interpreting scintigraphic images; and

"WHEREAS, such accuracy can be achieved in part by insuring the standardization of the performance of scintigraphic imaging instrumentation;

"BE IT RESOLVED, that scintigraphic instrumentation used to collect nuclear imaging data shall be quality control tested each day of use for minimization of variability in the following performance parameters:

a. Uniformity - the ability to produce a uniform image of a uniform "flood" source.

b. Spatial Distortion - the ability to image arrays of linear sources of radioactivity with a minimum of distortion.

c. Resolving Power - the ability to produce and display images of an array of radioactive sources which shall be discernible as separate entities."

Resolution 2 of August 1976 reads:

"WHEREAS, disposal records, while invaluable for compliance inspections, leave a question of accuracy;

"WHEREAS, once material has been disposed of, there is a tendency to forget completely about its location and amount;

"WHEREAS, disposal records are not required to be kept indefinitely;

"WHEREAS, constantly land is being placed into other uses;

"WHEREAS, many states have adopted the model solid waste disposal act which prohibits certain disposals by burial;

"WHEREAS, state radiation regulations should not be in opposition to other regulations;

"WHEREAS, regulations should not promote action unbeneficial to man and his environment; and,

"WHEREAS, should an exemption be deemed desirable, specific license conditions can authorize such disposal by burial as appropriate to the situation:

"BE IT RESOLVED, that the Conference petition the NRC that the blanket authorization for disposal by burial in the soil found in 20.304 of 10 CFR Part 20 be amended in its entirety. It is recommended that amendment be modeled after the disposal by incineration statement in 20.305 of 10 CFR Part 20."

The NRC staff has completed a preliminary value/impact assessment of the proposed amendment of 10 CFR 20.304 and NRC expected that a policy paper on this subject to be presented to the Commission by the end of the year.

In addition, NRC has responded to some earlier recommendations of the Conference. On May 3 and 4, 1976, in the course of the 8th Annual Meeting of the Conference of Radiation Control Program Directors at Springfield, Illinois, representatives of the States of Minnesota, New York, Oregon, Tennessee, Arkansas, New Hampshire, Pennsylvania, and Alabama met with representatives of the U.S. NRC Office of International and State Programs for the purpose of discussing certain items of mutual interest that concern Radiological Emergency Response planning related to fixed nuclear facilities. The representatives of the several States cited above believe, as a result of these discussions, that the Conference should formally direct certain yet unresolved matters to the Director of Operations for NRC for timely settlement. Here is a summary of the recommendations and NRC's response to them:

R: That the U.S. NRC make a determination of the most severe accident basis for which comprehensive radiological emergency plans should be developed by the offsite agencies.

A: The NRC/EPA Task Force on Emergency Planning is preparing a report on this matter. It is hoped to be completed in July of this year.

R: That following development of the aforementioned accident basis, the U.S. NRC supervise the activities of these Interagency Task Forces to the extent necessary to bring these Interagency Task Force report and training packages into consistency with the accident basis.

A: NRC intends to review the various interagency task force activities and if necessary, bring them into consistency with the report prepared by the NRC/EPA Task Force on Emergency Planning.

R: That upon development of [illegible] aforementioned accident basis, the Interagency Task Forces review and modify their respective reports and training packages for consistency with the accident basis.

A: NRC intends to review the various interagency task force activities and if necessary, bring them into consistency with the report prepared by the NRC/EPA Task Force on Emergency Planning.

R: That the U.S. NRC review the concept of "concurrence" with radiological emergency response plans for offsite consequences as developed by State agencies, in light of the voluntary and nonstatutory nature of the States' submittal, and in light of the site specific problems which are not necessarily compatible with the contents of NUREG - 75/111 (WASH-1293).

A: The NRC has interpreted the concept of concurrence, in Supplement 1 to NUREG-75/111 (March 1977). This supplement reduced the number of planning elements required for concurrence from 154 to 70. Although they obviously did not satisfy everybody with the 70 remaining elements, they did take into consideration the comments received from the Conference's Emergency Planning Task Force, which also reviewed the Guide and Checklist. They also factored in comments received from the U.S. Civil Defense Council as well as other Federal organizations. The supplement will be reviewed each year in January to determine if additions or subtractions should be made and, therefore, any comments that a State would like to make can be submitted anytime before next January.

R: That the U.S. NRC formally request of the appropriate Federal agencies the early development of guidance to the States in outstanding matters related to comprehensive radiological emergency planning, these matters including but not being limited to criteria for reentry, airborne particulate exposure, and exposure through the food chain, particularly through fresh fluid milk.

A: NRC believes the concerns expressed in this recommendation are being met. The EPA is currently developing criteria for PAG's for airborne particulate exposure and contamination and the FDA is doing the same for exposures through the food chain, including milk. The PAG's for airborne particulates are scheduled for publication as Federal Guidance by the end of 1977. The DHEW indicates the PAG's for food and animal feeds will be ready for publication in the FEDERAL REGISTER by mid to late summer of this year. With regard to reentry criteria, the EPA awarded a 2-year contract in 1975 to study this matter. The report from the contractor is scheduled for completion before the end of 1977, after which the recommendations will be reviewed by Federal and State agencies and also published as Federal guidance.

Other activities of the Conference during the past year were:

1. Larry Lloyd, the Chairman of the Task Force on Personnel Dosimetry, testified at the Washinton hearings on personnel dosimetry. Larry will serve as a consultant to the Federal Interagency Task Force on Personnel Dosimetry during the coming year.
2. Several members of the Task Force on Emergency Planning testified at a meeting of the Advisory Committee on Reactor Safeguards.
3. The Chairman testified before the Bureau of Radiological Health's Medical Radiation Advisory Committee.
4. The Chairman met with a representative of the Department of Defense regarding products containing radium.
5. The Conference notified GSA that more stringent requirements were needed before GSA disposed of thousands of products containing radium.
6. The members of the Conference met with representatives of ACR so that there would be a continuous dialogue between the Conference and the College. I believe that tomorrow's session is an indication of how much we have accomplished.
7. Members of the Conference met with a representative of ERDA several times during the year. These discussions will continue during this meeting. ERDA has shown great interest in certain activities of the Conference.

Before I close, I would like to say a few words about the Conference. This Conference has come a long way since that October night in 1968 when 24 State radiation control directors squeezed into a room at the Roger Smith Hotel in Washington. The reason that we have come this distance is that we have given strength to the State voices when meeting with Federal Executive Agencies or Federal Legislative bodies. By standing together, we achieved a position of influence and, consequently, we are now able to effect our own destiny.

It would be unfortunate if that position were to erode because of our failure to stand together. Do not allow minor differences to cloud your thinking about what this Conference stands for and what it can accomplish. The challenge to the State program directors during the coming years will be to stand together so that we will be able to protect the States' and the public's interests.

In closing, I would like to thank all of the members of the Conference for the work that was accomplished during the past year. Although much was accomplished, there are still a great number of unmet challenges. I hope that you will give Dale McHard, our incoming Chairman, the same cooperation that you gave me. I would also like to take this opportunity to thank the Board members, Dale McHard, Bob Will, Phil Brunner, Alice Dolezal, Jim Porter, and Frank Wilson for all the help that they have given me. Thanks should also be given to Bettye Swanson, the Conference's secretary, and to my own secretary Linda, who has worked diligently on behalf of the Conference for the last 7 years. Finally, I would like to thank those three workaholics, Jim Miller, Bob Augustine, and Shelley Schwartz, who performed so well in their liaison role between the Conference and the Federal agencies, and to Elmer Eisenhower, who was our liaison to NBS.

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES
PART I

William D. Rowe, Ph.D.
Deputy Assistant Administrator for Radiation Programs
Environmental Protection Agency

There have been a lot of changes, a lot of things happening in the last year. Not to say the least of which is that we have a new administration in Washington and a lot of new people coming in. We have a new Administrator at EPA, Douglas Costel, a new Deputy Administrator, Barbara Blum, and (not confirmed yet) I have a new boss named Dave Hawkins, who will be the new Assistant Administrator for Air and Waste Management under which the radiation program comes.

Very frankly, they have been very busy and have not had much time yet for radiation concerns. But I would like to say a few things about these people. Doug Costel is somebody who has been with the Government for a long time with OMB. He was around at the birth of EPA and he knows what we went through at the very beginning, how it started and what its changes are.

Barbara Blum is an environmentalist who has some very strong ideas, is very articulate, and very well informed. I am looking forward to seeing what she is going to be able to do in our area.

Dave Hawkins is primarily somebody with air program background. He comes from NRDC. At the Counsel of Environmental Quality we have Charles Warren, who many of you know from the hearings that took place in California on the nuclear issue. He was in charge of those hearings.

If you think the environmental movement is dead in Washington, you may be mistaken. I think, when I see who my supervisors are, and see what new people President Carter appoints, that there is a very strong commitment to the environmental movement. What this will mean to all of the programs and things that are going on, I do not know. But I think it is important that we understand that a commitment to radiation protection will continue.

In the past year we have accomplished quite a few things. First of all, our fuel cycle standards were promulgated. As Professor Maxey indicated, there are those who are not necessarily in agreement. Nevertheless, the standards represent many years of a public balancing, not necessarily based upon technical terms alone, but on social and political terms as well. These standards allow us to get on with other problems in the fuel cycle and perhaps put the planned releases problems out of the way. NRC is now developing regulations for promulgating these standards. The result of that standard being promulgated in this manner has more important implications. Namely, that NRC and EPA are working for the same thing, they both have specific roles and can find ways to work together effectively. The development of the final standard and the regulations that NRC is producing are making this evident. In fact, as a result of this effort on the fuel cycle, EPA and NRC have gotten together in almost every area of common endeavor, and have found a way where we can work as closely as possible for common goals.

This is particularly true in the area of waste management where we have responsibility for setting standards, the Nuclear Regulatory Commission has the responsibility for implementing regulations that implement our standards. In doing so, we have sat down with different task groups in NRC and EPA and developed what I would call common programs. Each of us has a role, each of us has milestones that have to be met if the other is to be able to get on with his job.

In the area of high-level waste, low-level waste and mill tailings, the Commission and EPA are developing common programs. By common programs I mean we are developing procedural methods of operating for what each of us must do and indicating how we will transfer information. That does not mean that we will necessarily agree with each other on technical matters. Each of us has our own operations and philosophies and this is to be understood. But at least we will be arguing technical problems, not arguing procedure or other things.

This procedure is extending itself to a number of other areas with NRC as well. We are working closely now on accident problems, and the Commission has undertaken to do a much more extensive study on total risks of radiation from accidents and from all parts of the fuel cycle. Not just class 9, but classes 3 through 8 as well, then they will get on to the problem of acceptability of risk as a separate step.

We are working together on development of development of emergency response planning and Protective Action Guides; of course, we have been all along. This is one of the first places where we had worked together. We will be undertaking the next aspect of our standards activity by looking at carbon-14 in the uranium fuel cycle. This will be a very closely coordinated effort. I think this represents a major step, at least it ought to, from the point of view of the States. I think States can come to EPA and NRC and see just what we are doing, how we are coordinating with each other, and how the interface between EPA and NRC and the States will take place. I do not see any major difficulties in this. I think we know where we are going and we are going there together. We each have our constituency, we each have our own responsibilities, but we ought to be able to reach them together.

In this light, there have been a number of other things that we have been working on. As you know, as it was mentioned previously, we did promulgate a standard on drinking water. In spite of it only being 5 picocuries per liter; it represents a levelthat is 2 picocuries higher than the public health guidance that existed beforehand. So, if you look at it closely, we actually have raised the standard in some respects. But we have also now put limits on manmade radioactivity as well. This is, however, one that we are watching closely, and will be revising as we get more experience and more data. The problem is the States are going to have to implement this program where they opt to take it on. The problem of States taking radioactive contaminants on along with the other contaminants is one that I know some States have already made some major inroads in getting underway. Some have not even started yet.

In January of this year, we published proposed guides to Federal agencies with a prescription in procedures for medical x rays for those Federal agencies. We have been getting extensive comments back. John Villforth and I met with Tom Gerusky recently, and BRH is going to make additional comments to our guidance, and we do hope to promulgate that in the near future.

We are working very hard to get out, by the end of this summer, guidance on plutonium cleanup. We have fairly well firmed this up and it is presently under final review.

The Protection Action Guides are moving and we are trying to get the particulate guidance out as well as to coordinate with BRH on food and water guides. Finally, we expect a report back soon from a contractor investigating the re-entry phase for Protective Action Guides. We hope to promulgate these as Federal Guidance in the near future.

Some of the biggest areas that we have been getting into are those involving naturally occurring radiation. As you know, we have undertaken extensive studies in Florida to look at the radium content in houses built on refilled land, using tailings from the phosphate mines which are high in radium and in uranium. We hope very soon to be able to come up with guidance in this area to allow those homes to be used and new homes to be built with, hopefully, a reasonable balance between risk and use of those facilities.

The biggest effort we are undertaking at the present time, and for which we have received a considerable increase in funds and overtarget personnel, is in the area of waste management. We have the responsibility to set standards for radioactive waste management. These will be environmental standards that will be neither site nor method specific. The first standard that we have undertaken to set is that for high-level nuclear wastes, and we intend to be able to promulgate that standard by the end of this year. Hopefully sometime during the time next year to finalize it. But before we set that standard, we have stepped back and we have said, "What are the guidelines and criteria that we should use to set standards for waste management, not just high-level waste, but all waste matter? What are the underlying things that we should take into account? What are the issues that we have to account for?"

To get at this problem, we have held two workshops. One was held in Reston, Virginia, and one was held in Albuquerque, New Mexico. The workshops were attended by interested parties from all sides; from industry, from government agencies, from various environmental groups, universities, and the public, members of the League of Women Voters, and people who came in off the streets. The format of the workshops was that after the introduction of issues, we got into smaller groups where everybody was equal and could say whatever they wanted. We were not sure what was going to come out of this. We were opening ourselves to a broadside. We did have to have thick skins to hear some of the comments. We were very surprised we did get some convergence of ideas out of these meetings. One of the more important ideas is that there is no such thing as zero risk; everything is risky. Nobody debated that. On the other hand, there were problems that we could not address very well. A critical one is what price do we have to pay for assuring credibility? Because of the problems that we had in the past, we may have to bend over backwards to assure the public that we are credible. What price do we pay for that? No one yet has been able to answer that question. I hope as we develop our criteria, it is a question that should be asked because it is an important criterion. We hope sometime around the late part of September or early October to come out and propose these so-called criteria. I say "so-called" because they will not have numbers in them, but they will be the set of precepts that we have to use in developing a numerical standard for high-level wastes.

As we go on to next year, we see the same kinds of problems continuing. When we finish with the high-level waste, we are going to have to attack the low-level waste problem and to do this in conjunction with the Nuclear Regulatory Commission. Then we hope to get on with the whole problem of mill tailings and after that decommissioning wastes. We only have limited resources, so, we have to do these tasks sequentially, we cannot afford to do them all at the same time. We have, I think, because of perception of risks involved, taken high-level waste first. I do not think they are necessarily as large a problem as mill tailings, but, nevertheless, the attention focused on this problem calls for it to be first.

With that as a summary, along with the idea that I want to leave with you that a new administration and some possible new budget impetus, we will come out from this next year as a very healthy organization. We hope to work very closely with the States to provide State support, as we have in the past, perhaps even with opportunities to increase it. But, nevertheless, we do see a future that is going to involve a lot of hard work and a lot of cooperation.

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES
PART II

Robert G. Ryan
Director
Office of State Programs
U.S. Nuclear Regulatory Commission

I want to talk to you about some serious things. I suggested in a news conference just prior to this meeting that this Conference may be the wave of the future as far as Federal/State regulations are concerned.

About a month after he took office last Janaury, President Carter sent a memorandum to the heads of all of his executive departments and agencies in which he renewed for his administration a commitment that he had made during the campaign. It is a document that is relatively short. I think, if I may, I would like to read a portion of it to you because it has significance to the whole question of Federal/State relationships.

It is dated February 25, slightly more than a month after the inauguration:

> "Throughout the campaign and transition period, I made a firm commitment to state and local officials that they would be involved in the development of my Administration's policy and budget priorities and programs. I pledged that such consultation would occur at the earliest possible stages in order to make it significant and fruitful.
>
> "That kind of state and local involvement is critical to the ultimate success of this Administration because:
>
> * State and local sectors constitute the delivery mechanims for most of the actual services the federal government provides;
>
> * State and local concerns, as well as their expertise, should be considered as programs are being developed in order to ensure the practicality and effectiveness of the programs;
>
> * Such early participation by state and local officials in our planning process will help ensure broad-based support for the proposals that are eventually developed;
>
> * It will insure that priorities developed at the federal level will work in conjunction with, and not at cross purposes to, priorities at the state and local level.
>
> "In order to insure that these objectives are met, please include in any major policy, budget or reorganization proposal which has significant state and local impact, a brief description of how you fulfilled this commitment on my behalf. It is not necessary to hold large and time-consuming public hearings or to establish large task forces to accomplish this goal. Selecting state or local officials expert in a particular issue and asking for their assistance in developing a program will often serve our purposes.
>
> "The most important part of this complicated process is that it is genuine and timely."

And it is signed "Jimmy Carter."

It fell to me, as the Office of State Programs director in NRC, to prepare our chairman's response to the President, and I pointed out the Agreement State program under section 274 of the Atomic Energy Act, which I am sure you all know about. And I also pointed with pride to our support, along with EPA, and the Bureau of Radiological Health, of this Conference. And we made a commitment as an agency to the President to a greater level of consultation with State and local governments, with State and local organizations in the future in all apsects of our work.

We meant what we said about the Conference, and we look forward to a long and productive relationship in doing what we are all pledged to do; that is, to serve the public interest and protect the health and safety of our citizens, and the environment in which they live, from radiation hazards.

We offer a few suggestions about how we should go about our business in the future. A couple of years ago I attended an environmental meeting in Colorado where Representative Morris Udall was speaking. And what he said on that occasion, I think, has applicability for our sessions today and later this week, and for our relationships in the future. He said that when it comes to relations between groups--and he was thinking, obviously, of environmental groups, but I think it also goes across the board and applies to relations between various levels of government--he said that we tend to be a nation of extremes; that we either indulge in uncritical love, or its opposite pole, unloving criticism. And what he called for, and what I echo today, is the middle ground, loving criticism; if you will, criticism in the highest and best sense of the word; a positive and not a negative virtue, a quality inspired by desire to see something good, prosper and become better; a quality that is characterized by candor and honesty. And what I think we ought to be looking for in our relationships is the kind of thing that you find in the successful family; a free and easy relationship, give and take, a good humor, and as I said before, loving criticism.

Now, it may come as a shock to you, but I would like to state for the record that the Feds are capable of making mistakes. Even the EPA and NRC and the Bureau of Radiological Health are capable of making mistakes. We are, after all, not infallible. And one of the great strengths of an organization such as the Conference, I think, is to bring to discussions of radiological health and safety matters a critical eye of the independent and practically experienced professional. And I underscore the word "independent." We do not need rubber stamps or claque or vassal organizations. And I hope you will be independent in the future. It seems to me that together we can do a great number of truly useful things to serve the public interest in the radiological field. I hope that this Conference will be a learning lesson for all of us, and an exercise in the kind of loving criticism I spoke about before.

REPORT ON FEDERAL ACTIVITIES IN MEETING TODAY'S CHALLENGES
PART III

John C. Villforth
Director
Bureau of Radiological Health

Bill Rowe and I have been through a rather traumatic time this week testifying before the Senate Commerce Committee. The Commerce Committee is holding oversight hearings on the Radiation Control for Health and Safety Act. The Committee is concerned with the broadest scope of the radiation issue, involving elements of the whole Federal establishment, questions of research in the bioeffects of microwave radiation, and the role of the Federal agencies working with the States. The Committee will have an opportunity to hear from the Conference next week since the Conference has been asked to testify.

There is also the question of the multiplicity of Federal radiation agencies and the conflicting role between some of these organizations. A question that Bill and I have been dealing with relates to the medical radiation issue; it is yet unresolved and we still have a difference of opinion that may have to be resolved outside of our agencies in spite of the desire of our respective agency heads that we work together as best we can to try to achieve a beneficial relationship so that those of you who have to deal with us are clear in how and who you should be dealing with.

One of the concerns that was put to us by the Senate Committee was that of the medical x-ray exposure, particularly the question of the excessive noncompliance to the x-ray performance standard. Now that there has been an opportunity to look at the results of the compliance testing of certified diagnostic x-ray, the question asked is: how successful is the standard and how successful is the compliance program? We find with considerable dismay (and the Committee called this to our attention) that there is a high degree of noncompliance with this new standard. This is significant noncompliance, not just improper labeling, and so forth. In some cases, overall noncompliance reached 30 percent of all the manufacturers. One particular manufacturer approaches 50 percent noncompliance. Most of this involves noncompliance of the assemblers.

The question is, how can we reduce this noncompliance? The Committee called to our attention that there were only 18 contract States to help us inspect the x-ray assemblers, and the Committee was very anxious to have us try to increase this. They put some very specific questions to us as to when and where and how we can get more States involved through cooperative contracts to improve the compliance effort. This is an area we will have to pay attention to. This degree of x-ray noncompliance is unacceptable. We will take regulatory action against at least one manufacturer because of the extent of noncompliance of his particular assemblers, and there are other regulatory actions that are going to have to be examined.

Tied into this is the need for amendments to the x-ray standard to meet changes of new technology and to improve some of the problems that we have encountered during this period of inspection. The x-ray performance standard is being examined for amendments. The problem of positive beam limitation is being looked into, and we will examine the effectiveness of this as it relates to the requirements that become applicable in 1979.

In addition to performance standards, there is a need for recommendations and guidelines to help the user come to grips with some of the issues that relate to technique. We have published guidelines on gonad shielding and chest x-ray recommendations, and we have published notices of intent to develop guidelines on x rays and pregnancy, mammography, and quality assurance. Guidelines on preadmission chest x rays, emergency skull x rays, and heart catherization are yet to come. We have reason to believe that we can make a significant contribution to dose reduction by looking at the efficacy of these particular examinations and then developing recommendations through the FEDERAL REGISTER system.

The data base that we will use to help us assess the magnitude of our success will be NEXT. It continues to be effective, and we are approaching the fifth year of operation. If you look at NEXT results, they reveal a success in the dental x-ray program quite clearly. There is a marked decrease in the exposures in dental x-ray over the past 4 years, which is attributed primarily to the work that you have done in the DENT program and the success that you have had in coming to grips with the dental x-ray issue.

Members of the NEXT Task Force and the Bureau will be manning a computer terminal this week and will be available to answer certain questions and show how the terminal can present some of these data to help you sort out and answer select questions that you might have on NEXT. The data are something that are useful to us, but we must use it with caution. We need to keep in mind that it does not answer all of the questions. The image receptor module that you have been testing is extremely effective. As we look at the question of the role of the image receptor in reducing exposure, we must have better information as to how the various film/screen combinations affect the exposures, so that we make recommendations to optimize the proper image receptor.

The NEXT data have been used in conjunction with Marv Rosenstein's adaptation of the Oak Ridge National Laboratory model of the anthropometric man. Therefore, we can now determine the dose for a variety of critical organs. We can couple this dose data with NEXT experience and with XES types of trends, and come up with some indices of relative importance of diagnostic procedures. We can rank these in terms of the numbers of procedures, the degree of success of reducing these procedures, and perhaps prioritize what actions we can develop in the future. I think this will be a very valuable way of optimizing our resources.

The importance of quality assurance in medical radiation has come to light in the last few years, and many of you have launched various programs of quality assurance. The DENT program is an example. There are 37 States now that are involved in DENT. The question now is, how do we export these types of successful programs to other states? The DENT program does show about a 40 percent reduction in dental x-ray exposures as a result of its application. We think the success of this is something that you should be extremely proud of.

The BENT program relates to mammography. It is a program that is cosupported by the National Cancer Institute. There are about 20 States and Federal institutions involved in this survey We have had seven training sessions this last year for 13 different States involving about 96 different people. We think this program will have the same degree of success as the DENT program. We have observed about a 20 percent reduction in mammography exposures as a result of the experience from the BENT program.

The quality assurance activity is an area where we can make big giant steps in the future. The Conference Task Force on Q.A. is coming up with important recommendations, but there is a need for more awareness and more coordination with you to better understand the kinds of techniques that can be applied to quality assurance.

A problem that is facing us is the reduction in our training resources, the essential elimination of the training short courses, and the limited availability of the regional radiological health representatives in EDRO to continue with the same degree of involvement in some of the use areas of medical x-ray. Therefore, we are going to have to look to other ways of communication. The video network that is being shown here in this Conference, on the TV's in your hotel room, and the video theater upstairs, are good examples of ways that might help to enhance that communication. We ask you to examine this means of communication closely to see if this is one we can pursue, perhaps with the collaboration of our sister Federal agencies. We encourage you to obtain the video tape decks to play these cassettes so we can increase the whole network of communication. We think this is extremely important.

One of the areas of interest to you is the technologist issue. Congress asked the Department specific questions with regard to its role with x-ray technicians. The Congress has before it a bill in the House and a bill in the Senate that would call for Federal licensure of technologists in the absence of State licensure. The Department has been reluctant to come to grips with that particular issue, the reason being, of course, that there has been a Departmental moritorium on licensure for allied personnel because it has been under study by a credentialing committee of the Department. That credentialing committee has just completed its report and it was signed by the Secretary. One of the recommendations of that report calls for certain national standards. If I may read recommendation 2 to you, it might help you understand what direction we have to undertake:

> "National standards for the credentialing of selected health occupations should be developed and continually evaluated. Professional organizations, other elements in the private sector and State governments, should play a significant role in this process. The standards thus developed should be utilized for the various purposes for which standards are required, including professional certification, licensure, private sector and civil service employment, and third-party reimbursement."

Tied to this, the Assistant Secretary for Health has advised the Commissioner's office that he is recommending that the Food and Drug Administration establish a national committee of experts in this area to address this issue and to come to grips with the questions of standards and licensure of radiologic technologists. So this might be moving more vigorously now that the Department Credentialing Report has been approved.

One of the bigger ways that we can reduce medical radiation exposure is through efficacy. But in order to have an impact on medical judgment, we must have a data base to understand the success of that efficacy program. This will facilitate an analysis, on a cost/benefit basis, to see if the recommendations can be successful.

An example might be the work that was done here at the University of Washington; specifically, the work that was started by Dr. Loop and carried on more recently by Dr. Phillips, concerning the efficacy of skull x rays ordered for emergency admissions. Dr. Phillips' work indicated that with proper selection criteria, he was able to effect a 40 percent reduction in the number of skull films that were ordered in the emergency room of the University of Washington Hospital. The question of whether that success is transferable to other institutions around the country has to be tested. Dr. Phillips is extremely conscientious and dedicated, and it takes that type of a commitment on the part of clinicians to be able to effect this type of success. But if this were transferable to the rest of the country, and if one were able to get at least a 40 percent reduction in the number of skull films, one might achieve something like a $50 million a year saving just on the cost of the procedures, not realizing that in addition, there is a cost saving associated with the elimination of the insult to the people who have been x-rayed unnecessarily. This is an example, but it is an example that illustrates that a considerable amount of effort must go into determining the data base before one can make those sorts of decisions, and we must pursue these types of efforts in the Bureau and with our colleagues in the professional circles.

This whole question brings us to another area that Gerry Parker was talking about, and that has to do with cost containment. The Commissioner of the Food and Drug Administration and the Secretary are very interested in this issue, and are very interested in the role that radiological health could play in cost containment. We think that we will have an opportunity to brief the members of the Department on this subject in the near future. We think that this is something that you should give careful consideration to presenting to your respective agencies, particularly as it comes to budget time since it illustrates the value of your program, not only in reducing exposure and the cost of ill health from the radiation insult, but also for the cost saving from the elimination of repeat examinations. Let me give you examples of how this might work.

If one were to apply an effective quality assurance program around the country and could eliminate the retake rates that we have experienced, which can amount to from 10 to 15 percent in some institutions, one might achieve something like $10 to $100 million a year savings in the cost of film and chemicals alone. This assumes an average cost of $3.50 per film. You include the technologist's time, the radiologist's time, and so forth, and the saving can be even greater. But $10 to $100 million in savings is not unreasonable.

Let's look at the question of x-ray in pregnancy. Through proper guidelines and selection of patients and procedures during pregnancy, one can get a reasonable reduction in the examinations for women who may be pregnant at the time of the examination. One could eliminate something like 100 cases of childhood cancers as a result of more careful selection of the patient. This, again could be translated to a cost of ill health that might be something like a million dollars.

One could take the example of nuclear medicine, of iodine-123 as a substitute for iodine-131. If there are 200,000 thyroid scans being done each year, and if one looks at the insults from these, one could predict as much as 200 cancers might be saved each year if one used iodine-123 versus iodine-131. Those 200 cancers would translate to perhaps $2 million a year in savings of direct health care.

If you examined the quarter of a billion diagnostic x-ray examinations that are done during a year, the cost to the consumer can amount to $6.3 billion. Some have predicted as high as a third are unnecessary, and therefore something like $2 billion can be saved.

I think it is unrealistic for me to suppose that by working out some guidelines with our colleagues in the medical profession that we could get this kind of a reduction, but the potential of using our resources to have a significant impact on the direct health care through this is something that we have not adequately explored, and I think we must explore. We must explore that at the same time we keep present in our mind the fact that we will be eliminating some of the ill health, cancers, and insults to future generations as a result of misuse of radiation. I think this is an area we certainly want to move into; an area that we look forward to working with you on.

Last year, there was some confusion expressed about the possible conflict that we were having, or appeared to be having, with the Bureau of Medical Devices and Diagnostic Products. I indicated at that time that the Commissioner of the Food and Drug Administration had expected us to work out our relationship with the Bureau of Medical Devices and Diagnostic Products such that this would work to the best interest of the agencies. As a result, the Deputy Commissioner has approved a memorandum of understanding that Dave Link, the Director of the Bureau of Medical Devices and Diagnostic Products and I have worked out. I would like to quote to you a portion of that memorandum. Basically, it says that there are some administrative procedures that have to be worked out as it relates to the implementation of the medical device amendment. But once those are worked out, the memorandum states:

> "The Bureau is to be the lead bureau in FDA dealing with manufacturers of the following types of medical devices:
>
> "A. All medical devices which are electronic products subject to the Radiation Control for Health and Safety Act." (That is, x-ray machines, medical lasers, and conventional devices, for example.)
>
> "B. Medical devices other than electronic devices subject to the Radiation Control for Health and Safety Act, but which emit ionizing radiation essential to the intended function." (Cobalt 60, teletherapy, brachytherapy sources, and so forth.)
>
> "C. Accessories or components, with products falling under categories A or B, which may influence the quantity, quality, or direction of the radiation emitted or produced." (That is, x-ray film, screens, image receptors, film processors, nuclear medicine scanners, et cetera.)"

So the Bureau will be given responsibility under the Medical Device Amendments in collaboration with the Bureau of Medical Devices and Diagnostic Products to be the lead bureau in FDA for these three sets of products. This means, of course, that we will have to take on a newer responsibility as it relates to mechanical safety, electrical safety, and, more importantly, the efficacy question, which is inherent with the Medical Device Amendment--this efficacy question of the use of certain medical devices. We think that this broadens the base, we think that this will allow for a centralized program in FDA, and we hope, a program that, in collaboration with the work that you are doing, will be very instrumental in successfully reducing the radiation exposure and thus meet the challenges of today and tomorrow.

SESSION: ISSUES IN MAMMOGRAPHY

Moderator: *Gerald S. Parker*, Massachusetts

PATIENT REACTION TO THE MAMMOGRAPHY CONTROVERSY
Rose Kushner, Author, Breast Cancer: A Personal History and Investigative Report

WHO SHOULD HAVE MAMMOGRAPHIC EXAMINATIONS?
Richard G. Lester, M.D., Department of Radiology, University of Texas

NATIONAL CANCER INSTITUTE'S GUIDELINES FOR MAMMOGRAPHY
Winfred F. Malone, Ph.D., National Cancer Institute

RISK FACTORS TO CONSIDER IN SURVEYING ASYMPTOMATIC WOMEN
Albert W. Hilberg, M.D., Division of Medical Sciences, National Research Council, National Academy of Sciences

WHAT CAN AND NEEDS TO BE DONE BY STATE/LOCAL RADIATION CONTROL AGENCIES
Alice Dolezal, Section of Radiation Control, Minnesota Department of Health

SESSION: WHERE DO WE STAND ON COMPUTERIZED AXIAL TOMOGRAPHIC SCANNING?

Moderator: *B. G. Brogdon, M.D.*, New Mexico

CT SCANNING'S PLACE IN DIAGNOSTIC RADIOLOGY
Ronald G. Evens, M.D., The Edward Mallinckrodt Institute of Radiology, Washington University School of Medicine

HOW WILL CT SCANNING AFFECT PATIENT TREATMENT AND CARE?
H. David Banta, M.D., M.P.H., Office of Technology Assessment, Congress of the United States

PLANNING ASPECTS OF CT SCANNING
Patricia A. Gempel, Senior Professional Staff Scientist, Arthur D. Little, Inc.

EXPOSURES AND STANDARDS
Roger H. Schneider, Division of Electronic Products, Bureau of Radiological Health, FDA

STATE RADIATION CONTROL CONCERNS
Gerald S. Parker, Assistant to the Commissioner (Radiological Health), Massachusetts Department of Public Health

Preceding page blank

PATIENT REACTION TO THE MAMMOGRAPHY CONTROVERSY

Rose Kushner
Author of
"Why Me?: What Every Woman Should Know about Breast Cancer to Save Her Life"

I would like to give you a little information about my personal background before beginning, so you will understand how and why I was able to wade through all the contradictions and controversy surrounding mammography. I worked at The Johns Hopkins Medical School and am a frustrated physician. I had always hoped to be an M.D. but by the time I was married and had a husband who could have paid my tuition, I had decided it was more fun to write about medicine than to practice it. However, during the years I had worked at Hopkins, I dated a good many medical students, and one does not date medical students for 4 years and wind up being afraid of doctors.

That was the first legacy of my medical-school years. I also learned the jargon. Although it was psychiatric jargon, it is still medicalese, and it was a great help to me when I had to find out what to do about myself. In addition to writing about psychiatry and other medical issues, I wrote--and still do write--for the American-Jewish press. This may seem like a non sequitor here, but I am inserting it as an introduction to an unlikely analogy between the two subjects.

Whenever something curious or peculiar or just plain idiotic came up in Jewish issues, I used a handy medieval myth from legends as a mechanism for showing how silly the whole business seemed to be. This myth concerns a (naturally) mythical town in Poland called Chelm where the people were exceedingly "intelligent." For example, they once had a heated debate about what is more important: the sun or the moon. Finally, after months of angry, sometimes vicious, arguments, the brainy residents of Chelm voted on the matter, and the "moonies" won.

Why?

They said that since the sun appears only during the day when it is light anyhow, there was no need for the sun at all. However, the nights (there were no streetlights in Chelm) were black as pitch, and, without the moon, no one would be able to see a thing. Naturally then, the moon was far more important.

The sun-moon argument caused a deep schism between the sunnies and the moonies, and the Chelmers decided to build a second synagogue to separate the two factions. After the foundation had been dug and the new building completed, the people realized that there was a gigantic mound of earth in the town square. Again, there was a fight about the best way to get rid of the tons of dirt.

The Chelm solution? "We will dig a huge hole outside the town walls and bury the mound of earth." This transfer of dirt went on endlessly for centuries, and the countryside of Poland is still dotted with the mountains and hills that were formed by regular transplantations of Chelm soil.

Chelm and its solutions to problems reminds me of what we are doing here today--and probably will be doing for months, maybe years--while discussing the mammography of women under the age of 50.

For example, everyone now knows that x radiation may be of some miniscule risk (I do not care whether it is 0.00007, 0.0007, 0.007, or whatever) in women under age 50. There are also reliable data showing that mammography is frequently not effective in detecting breast cancer in younger women (as it was in my case: a "false negative"). Under these circumstances, it seems to us women that there should be no controversy at all for premenopausal women. Yet, in spite of these data that most informed women now know, the American College of Radiology and the American Cancer Society are still insisting on routine screening of asymptomatic women under age 50. To us, it seems as if these advocates of routine screening, like the intelligent residents of Chelm, are just digging more holes, getting more dirt to put into another hole. True, we may not be getting the whole story. If we are not, then it should be given to us. In the meantime this is the way we see it.

Before going further, I would like to point out to any radiologist listening to me today that a mammogram has become a piece of "defensive medicine" being used by obstetricians and/or gynecologists (because they are usually the primary deliverers of health care to American women) to get off the legal hook. I do not know if you have given this much thought, but I have been involved now in three medical malpractice cases. Two of them concern "delayed biopsy," and the gynecologist-defendants argued successfully that as soon as the women had been referred to radiologists for mammograms, they were no longer legally liable for negligence or malpractice. The burden was entirely on the radiologists for not detecting the existing breast cancers.

In addition, there was one case where the woman had had a "suspicious" mammogram and a mutilating biopsy was performed by her surgeon. She sued for excessive mutilation. The lesion had not been malignant, and the radiologist was held at fault because he had not encouraged the patient to get a second opinion on his "suspicious" diagnosis before having the biopsy. These cases never reached the courts; they were all settled without juries or judges and, therefore, there was no publicity about their outcomes. For this reason, I thought I would tell you some of the legal aspects of mammography you may not know about: The average gynecologist is probably turning women over to you for breast x rays to shift the burden of legal responsibility for a possible misdiagnosis. Very likely, there will be more and more of these kinds of legal cases coming along as more and more women are mammographed, biopsied and possibly mastectomized as a result of screening programs. So I think it is only fair that you know that you may well be the "fall guys" (or "fall girls") for some of these kinds of malpractice cases. Gynecologists are not legally liable once they refer a woman to a radiologist for a mammogram. Of course, radiologists can probably get off the hook by immediately referrring women to surgeons, I suppose. At this time, I do not know who would be legally liable in this kind of a case, because I have not been involved in one. And, since the issue is so new and since so many such cases are settled out of court, neither you nor I may ever know anything about them at all. Still, they do happen.

On Friday, June 17, 1977, I testified before the Senate Commerce Subcommittee on Mammography. I would like to tell all of you here that I do not think any of the Senators who were present even know what mammography is, but they will undoubtedly soon have to find out. I would, however, like to tell you today what I told the Senators--leaving out odds and ends like the difference between a rad and a roentgen, which I assume everybody here knows, although the Senators did not. The first thing I did, of course, was to identify myself. The second thing (and this is where I think my colleagues in all the media have fallen down dreadfully) was to distinguish clearly between diagnostic mammography and screening by mammography. This distinction, I think, has not been clarified strongly enough to American women. If a woman has a sign or symptom of breast cancer, she is, obviously, not being mammographed as a "screenee." Unfortunately, the Breast Cancer Detection Demonstration Projects (BCDDP's) did not help too much in this regard, because--as of December 1976--of the 260,000 or so women who had been "screened" at that point, there were about 55,000 who were symptomatic by anyone's standards. That is, they had lumps, thickenings or nipple discharges--what the National Cancer Institute calls "overt symptoms of breast cancer." This figure does not include women who have family histories of breast cancer or a personal history of biopsies or benign breast disease. They had frank symptoms of breast cancer when they entered the BCDDP's, and they have no business to be considered screenees at all. This kind of semantic situation had clouded the issue for many American women, because, of course, diagnostic mammography is one thing and screening of asymptomatic women is quite another. As far as I know, there is only one controversy surrounding mammography, and this involves routine screening of asymtomatic women under the age of 50. This was something that had to be pointed out to the Senators, and must usually be pointed out to women as well.

The Senators also had to be told how serious breast cancer is and how many women die from it every year. They had to be told why early detection using mammography (or any other technique) is essential and could be a lifesaving examination, because a tumor might be found preclinically before the malignancy has spread into the regional lymph nodes or other organs of the woman's body. I was surprised and I think you will be surprised to learn that many people--including the Senators--did not know that breast cancer is so prevalent or so fatal.

I also went into the backgound of the HIP Study. I assume that everyone here knows that fewer of the women in the study group, i.e., those who had been screened by mammography, died of breast cancer in the 7-year period after the Study began. In addition, I told the Senators that about three-quarters of the women in the study group who were found to have breast cancer did not have metastatic disease in the nodes, while the women in the control group had the general 50 percent statistic in terms of axillary invasion. I also told them something that you may or may not know. According to the statistics from the HIP Study, the total life-saving effect of mammography was seen in women over the age of 50. There was absolutely no difference in the survival rates of those younger. I will repeat. The total gain in years of extra life was found in the women over the age of 50.

Next, I talked about the origins of the BCDDP's and how they were more-or-less limping along until Mrs. Ford and Mrs. Rockefeller had their mastectomies in the fall of 1974. During the months after that, women began to line up everywhere to get mammograms. Perhaps you do not know all that happened in Bethesda at the time this was first begun. According to Dr. Arthur I. Holleb, Senior Vice President for Medical Affairs of the American Cancer Society, the mammographic screening programs were begun as a unilateral program by the American Cancer Society. The Society's plan was to have 12 Demonstration Projects supported entirely by the ACS, but, when the NCI agreed to become a cosponsor, this was expanded to 29 screening centers in 27 cities. At that time, the BCDDP's were not under the Division of Cancer Control and Rehabilitation (DCCR) but were being managed by the Diagnosis and Detection Committee (DDC) of the Breast Cancer Task Force. It was poorly set up, I told the Senators, with no thought to possible carcinogenicity of the x radiation, no coordination with the Bureau of Radiological Health or the BEIR group at the National Academy of Sciences. (On June 17, this was an opinion that has since been, I think, supported by events that have taken place since then.) Dr. Robert Egan from Emory, who was one of mammography's early pioneers, along with Dr. Gershon-Cohen, told me himself that he felt the BCDDP's had not been given enough thought and that the HIP Study was not established to produce any solid statistical data. Nevertheless, HIP definitely outclassed the BCDDP's. For one thing, the women were randomized. In the BCDDP's, the screenees were entirely self-selected.

To give you an example of the inadequate thought that was given to the BCDDP's, I would like to mention that the DCCR is now attempting to obtain the personal risk histories of the 260,000 plus women who are participating. It is clear now that the whole issue has boiled down to a matter of what women should be screened, aside from age. Having a personal or family history of breast cancer is known to be a high-risk factor and so is nulliparity, early menarche, and so forth. However, there are, as yet, no weights attached to these risks to enable experts to determine who the high-risk women really are and who should be screened periodically, regardless of age.

In addition, there was little or no uniformity in the way the epidemiological data were obtained from the women. Vital information like family history and exposure to various carcinogens was so completely messed up that really, the only thing to do is to throw them away and start all over. In some Projects, there were rather lengthly and detailed histories taken by professionals; in some, they were skimpy and taken by Reach to Recovery Volunteers of the American Cancer Society; in others, the women filled out their own. As a result, there is such a statistical knot that the data management personnel at the DCCR, the people who are supposed to analyze these 260,000 plus forms, are having a very hard time making any sense of them at all.

From an ethical point of view, there were no informed consents given to any of the participants. There are forms now, and attempts are being made to cover every ethical consideration. But there were none at the beginning, nor were there any in the HIP study. According to Dr. Philip Strax, who was involved in both the HIP Study and is a Project Director in the BCDDP in New York, and Dr. Holleb of the ACS, everyone knew that there was some irradiation hazard involved, but it was considered to be minimal and of no importance. A Dr. Harris of the New York Department of Health had told Dr. Holleb that he did not think it was above the level considered safe, and Dr. Holleb does have a letter from a person from the NCI who supported this view. For this reason, the ACS and the NCI--knowing that there might be some danger--went ahead with the BCDDP's. However, none of the women involved were informed that there might be any risk whatsoever.

This information may be something that radiologists in this audience must know because, again, you are running into a legal risk. If you do not tell a woman that she is being exposed to a possible carcinogen, she may well come back and sue you because you did not tell her. Certainly, the HIP Study people face this, and so do the BCDDP's. So do all radiologists in private practice or in hospitals. I certainly hope you are having your equipment inspected, calibrated, use low-dose film, proper screening, and so forth, and most important, tell your patients that they may be exposing themselves to a minute risk. And, I would suggest you get this in writing.

To get back to the BCDDP's, they grew like Topsy after the fall of 1974 and were ill-prepared for the flood of publicity that came after the Betty Ford-Happy Rockefeller mastectomies. In my testimony before the Senate I presented some of the news stories that appeared at the time. Here is a piece from The New York Times, headlined: "Breast Cancer Project Called Success." Here is another one from the Milwaukee Journal: "This Project's a Lifesaver." Another, "Expert Defends the Safety of Mammograms." And so it went. I cannot even begin to estimate how many times Barbara Walters and other people on television and radio urged women everywhere to rush to their nearest mammographer and be screened for breast cancer. How many feet of film and minutes of radio time were spent on this really poorly tested medium, I have no way of knowing. But women were besieged.

I will now read what I read before the Senators on June 17, because I think you might be interested in knowing it. I said:

> "Within a matter of weeks," (this refers to the time after the Ford/Rockefeller mastectomies) "women all over the country were inundated with information about this life-saving machine, and waiting lists for mammograms were often months long. Omitted from this flood of media coverage, however, was the behind-the-scenes conflict among scientists about the potential danger of exposing healthy breasts to a known carcinogen: x ray. It has been known since the days of Madame Curie that radiation causes cancer, and that its effect is cumulative.
>
> "In addition to the knowledge about the carcinogenicity of radiation, breast-cancer experts knew that relatively large doses of x rays were required to penetrate the soft tissue of the breast, and that because of the complex physiology and anatomy of the organ, it was exceedingly vulnerable to any carcinogen. In essence, the arguments of the opponents of the BCDDP's was that radiation may actually cause cancers to be triggered, and that the risks of mammography outweigh the benefits in large populations of women. However, none of us women knew anything about this controversy that was swirling around our breasts, and we waited--blissfully ignorant--to have our mammograms taken.
>
> "In January 1975, Dr. John C. Bailar, III, the editor of the Journal of the National Cancer Institute, published his views in another medical journal, 'The Annals of Internal Medicine,' arguing that the HIP Study had not shown any increase in survival rates

among the women under 50." (This, of course, is what I mentioned earlier as a result published by the Study's own statisticians.)

Since Bailar published his paper, he had modified his views because radiation doses have been lowered, low-dose film is being used and the risk to women has, therefore, been considerably reduced. I am certainly not John Bailar's spokeswoman, but I would like you to know that he has moved with the times and has altered his views. I also appreciate the fact that radiologists have altered their views. However, I do feel as a woman and as a breast-cancer patient a debt to Bailar because he raised the issue in the first place, and I feel that if he had not, there might not have been such a quick move to expose our breasts to as little x radiation as possible.

But, going back to January 1975, we women do not read The Annals of Internal Medicine were still unaware of the controversy. It was all going on behind the scientific scene, there was no mention in the lay press. The only reason I knew anything about it is because I do read the medical press, and I live only 5 minutes away from the NIH. While the Bailar paper did not reach the general public, it did expose the pros and cons of the mammography screening program to the point where Dr. Frank J. Rauscher, Jr., former director of the NCI, appointed a committee of prominent investigators to analyze the HIP data and to determine if screening by mammography did do more harm than good. And, as you know, Dr. Lester Breslow did the epidemiological work and Dr. Arthur C. Upton--the new director of the NCI--did the extrapolations from the BEIR Report which will be discussed later at this meeting. It was found that in Nova Scotia, 208 women who had tuberculosis were fluoroscoped from the front instead of from the back and, of these, 36 women developed breast cancer. Of 493 women who were not so fluoroscoped for tuberculosis monitoring, only 8 women developed breast cancer. Another study involved women from New York who had been given x-ray treatments for chronic mastitis after pregnancy, and those who were irradiated had twice the number of breast cancers than did the women who were not irradiated.

There was also a study of a study done in California of women who had been treated by x radiation after breast-cancer surgery. Their healthy, remaining breast was irradiated--just in case. In this group of women (I am taking all this information from the NCI report), there was considerably more cancer among the women who had this irradiation than in those who did not.

As you may know, the Breslow and Upton sections of the HIP Study analysis were presented on July 19, 1976, at a meeting held at the NCI. The third section--the pathology report--was not submitted on that date. Dr. Louis B. Thomas, Chief of Pathology at the NCI, and his committee members had had a great deal of trouble collecting all the old slides from the various hospitals. So, on July 19, only the Breslow and Upton reports were issued. Apparently, these results were enough, because on August 23, 1976--against the violent objections of just about everybody--Dr. Diane Fink and Dr. Arthur Holleb issued a "Dear Doctor" letter limiting the number of women under age 50 to be screened by mammography in the BCDDP's. Subsequently, there were press releases issued by the Office of Cancer Communications (OCC) saying that women under the age of 50 should not be screened routinely by mammography unless they had had breast cancer themselves, had an immediate family history of breast cancer, had chronic cystic disease, had a personal history of benign breast disease and so on and so forth.

There "interim guidelines," by the way, applied only to the 29 NCI-ACS BCDDP's. Now, according to the Bureau of Radiological Health, there are somewhere between 5,000 and 6,000 mammography machines being used in the United States today. With the minimum figure as a base, this means that the NCI guidelines did not affect the other 4,971 pieces of apparatus in doctors' offices, hospitals, or clinics. So millions of us women in the United States were not protected by that "Dear Doctor" letter of August 23, 1976. By that time, however, there was so much media publicity that women were so alarmed that we became cautious and often stopped having our breasts x-rayed even when it was imperative. For example, it is so bad now that women--like me--who should be screened, because we have already lost one breast, are not permitting ourselves to be mammographed. In addition, thousands of women who have palpable lumps or other overt symptoms of breast cancer are also not permitting themselves to be mammographed. Clearly, something has to be done about this situation. This is an awful mess that we are in now. The media have, unfortunately, often confused the issue by too much advertising and then by too much anger. As I mentioned before, the distinction between diagnostic mammography and screening is usually not made clear. On the other hand, radiologists have not done much to keep us women informed, nor have they voluntarily assured us that their equipment exposes us to the least amount of x radiation necessary, should we meed mammograms.

Unfortunately, radiation-controllers--all the "watchdogs" in government agencies who are supposed to protect us from excessive x radiation--have not done much more than have a lot of meetings and conferences.

As a medical reporter with a personal, as well as a professional, interest in the mammography fracas, I have gone to almost all of these meetings and conferences--including the one where Dr. Rauscher asked the employees at the NCI what they would do. I became curious about the non-role being played by the Bureau of Radiological Health, which was established in 1968 as a result of legislation. Supposedly our supreme watchdog agency over all medical applications of radiation, the BRH--it seemed to me--should have been very much involved in all the arguments. So I asked what the Bureau of Radiological Health was doing. And if it was doing anything or saying something, why were not the Bureau's opinions or recommendations being included in the discussions? Why was it only the American Cancer Society and the NCI that were running the BCDDP's? Was the BRH doing anything?

Well, I spent a day out in Rockville and found out some very interesting things. Yes, the Bureau was trying to do something. It is tax-supported, has a lot of tax-supported experts who were trying to have some input about mammography, but nobody seemed to be listening. The Bureau of Radiological Health has 350 people in the entire country and it was, at that point, hoping to be able to have 15 to work only on mammography. Did they ever get the 15? (This was addressed to Mr. John Villforth who replied; "No; well, fewer than 15 people to take care of an awful lot of breasts in the United States.")

Here is just one example showing how no one was listening to the Bureau. Ron Jans, a BRH physicist, had published a paper in which he cited data collected by Henry Bicehouse regarding 70-odd random medical facilities in Pennsylvania. In those 70 random medical facilities, the radiation being given to women in routine mammography ranged as high as 47 roentgens per exposure. I had learned that a roentgen is not a rad. We women have only been told about rads (and I had to explain rads to the Senators), but we had never been told anything about roentgens. Instructions given to women--when given to women--are, "ask how many rads you are getting." No one ever asks a woman to find out how many roentgens she is being given or exposed to, and she certainly has no way of knowing unless somebody tells her. Radiologists have no way of really knowing how many rads a woman's breast is absorbing at its midpoint, but they certainly know how many roentgens they are giving to us. How do radiologists know about roentgens? They measure their kVp's and their mAs's. This is what I learned at the Bureau, that day, because I did not know a nmAs from a kVp at all prior to my visit. Above all, I knew nothing about molybdenum versus tungsten tubes, screens or about the stale chemicals that may affect the resolution of a mammogram.

I was taught a great deal that day at the Bureau of Radiological Health, and since then I have been trying to teach women the same kind of technical stuff about mammography that I learned. It is complicated to attempt to compute the number of rads a woman might be getting, even if her technician knows the precise number of roentgens he/she is giving to you. But, as I learned at the Bureau, the technician does not often know how many roentgens he/she is giving to a women. This is one of the big problems of the whole business: the radiation technologist.

What I told the Senators last June 17th I would like to pass on to you. I see mammography as photography. A camera is the mammograph, and it can be a Leica or a Brownie. A photographer can use excellent, fast film like Tri-X (low-dose film), or a photographer can use slow film like Plus-X or high-dose film. There can be a lot of sun--a large output of x radiation--or a cloudy day--a minimum output. But it is, in the end, the photographer who counts. I would bet any amount of money that if I took a picture with a Leica, on a bright, sunny day, using fast film, it would be awful when compared with a photograph taken by Eisenstadt or Steichen using a Brownie Instamatic. It is, in the final analysis, the technologist (photographer) who makes the difference.

The radiologist is important, too. He/she is the art critic who comes in at the end of the procedure and evaluates the picture for its merit. It is the radiologist who decides if a particular spot is suspicious or nothing to worry about. But it is the technologist who prepares the picture for the radiologist to judge. And right now, there are only three States that license technicians: New York, California, and New Jersey. I know there is an American Registry of Radiological Technicians (ARRT), but membership is not required in most of these United States in order to get a job as a mammographer. For example, I answered a blind ad in my own State of Maryland, and the only thing I was asked was how much money I wanted as salary. I was not asked my experience, I was not asked my training, where I went to school--nothing. All I was asked was the number of dollars that I wanted. My daughter, on the other hand, wanted to get a summer job and I suggested that she try to get one as a shampoo girl in a beauty shop. It turns out that, in the State of Maryland, shampoo girls must go to school, take very extensive examinations on hair chemistry and whatnot and pass examinations to get a license.

And that is just to wash someone's hair!

We have 54 entities in this country, including Guam, Puerto Rico, the District of Columbia, and the Virgin Islands. It is really outrageous that a shampoo girl must be accredited by examination in order to be licensed while a radiological technologist who exposes people to potential carcinogens is not. I know that there are no laws governing this situation, but radiologists must police themselves. If radiologists do not police themselves properly in order to protect the public, then radiologists must expect that there will be such laws enacted.

The Senators on the Subcommittee asked me to suggest to them what could be done about this kind of problem. I confess I felt silly, but I suggested using the Medicaid-Medicare system as a lever, because it is Federally controlled. I know this seems extreme, but it is--as far as I can now see--the only way we ordinary younger women can be sure we are being mammographed with the best possible equipment by the best qualified personnel. It seems unlikely that radiologists would use one set of equipment and staff for Medicare patients and another set for us people who pay our own way. I know radiologists will not like this idea, but if they wish to avoid this kind of governmental control, they will have to find a way to solve these problems themselves. Otherwise, radiologists will have to expect greater control on the grassroots level.

When I talked to the Senators about equipment, I mentioned the voluntary dosimetry program that the Bureau of Radiological Health is sponsoring: The BENT program. BENT stands for Breast Exposure: Nationwide Trends, and has been in existence a relatively short time but appears to be growing quickly (by BRH standards). The DENT program to monitor dental equipment has been in existence for almost 4 years and--big deal!--there are 30 States involved. If so few dentists have been persuaded to participate in almost 4 years, it looks as if voluntary monitoring of equipment is not high on the list of radiological priorities. Frankly, it seems to me--as a mere woman--senseless that all radiologists do not participate. After all, it costs no money, requires only that a radiologist put a plate on the equipment and return it (postage-free) to the Bureau. Experts in Rockville will then tell the radiologist what is wrong with the equipment that was used. All for free! What more could anyone want?

Aside from the technical aspects of the radiological part of the mammography program, I am very concerned as a woman because of the information that came out in the pathology report, finally completed in March 1977. I do not like to use the word "suppressed," but anyone who wanted to see it really had to run after it to get it. (I think Dr. Hilberg will go into that aspect in greater detail later.) One point that came out in the pathology report was that there were masses--benign and malignant--a couple of them more than 4 centimeters in size, that were not found by clinical examination. They were picked up by mammography. That led Dr. Thomas et al. to concude that the HIP Study results were an example of the comparison between excellent mammography with poor clinical examination. This was the conclusion of the pathology committee, and I have no opinion other than what I read in their report.

In addition, eight of the "cancers" found in the HIP Study turned out not to be cancers at all: they were miscellaneous benign lesions. Nonetheless, those women were given radical mastectomies. There were also 17 in situ cancers found among the 44 that were found by mammography only. Many experts felt that these premalignant lesions frequently never become frank cancers at all and--had they not been found microscopically by the sensitive mammograph--these women would never have had mastectomies at all. As an example of what I mean, I would like to tell you that one detection center I visited had a "prevalency rate"--the rate of suspicious mammograms--that was about 10 times the national incidence rate of 7 percent. Assuming that the screening programs--by definition--would pick up many preclinical cancers, one would conclude that this prevalency rate would be higher than the normal incidence rate. But a factor of 10 is simply too high. It seems to me, and to many people who have real expertise in the statistics of this kind of situation, that a prevalency rate that is 10 times higher than the incidence rate is proof that mammography is picking up many cancers that will never grow. Of course, at this time, the treatment of in situ cancers is controversial because there is no way to know which will some day become invasive and which will not. In my opinion--as a woman and as a patient--I think that the decision should be given to the woman to make and that the surgeon has no right simply to remove the breast on his own initiative. If the patient wants to gamble that the in situ lesion (removed entirely by the biopsy) was all the cancer present in her breast, it is her privilege to wait. No one would take my breast off on the basis of a cluster of in situ cells, I can tell you that positively!

To summarize, what I told the Senators on June 17, 1977, I would like to tell you as well.

1. If the different State governments and the Bureau of Standards have the authority to inspect weights and measures in grocery stores and in butcher shops all over the United States, why cannot the Bureau of Radiological Health walk into a radiologist's office to check the equipment that exposes our breasts (and a man's testicles) to carcinogenic x radiation!

2. Why are there not Federal laws requiring that all x-ray technologists pass a qualifying examination, repeated every 5 years or so, so we women can be sure that the person pushing the buttons knows what buttons to push? (I think Senator Jennings Randolph has already introduced legislation on this matter, as a matter of fact.)

3. With all the talk of the new films that require less and less radiation in order to obtain a good image, how can we women be sure that this reduced radiation level is not so low that it misses a microscopic cancer entirely? After all, a false negative--like mine was--is more dangerous to us than is the worry that we will trigger something that will be found 20 years later.

4. If mammography is unreliable in young women because of the anatomy and physiology of premenopausal breasts, why expose them to any x ray at all--no matter how miniscule the risk may be?

5. Is it possible that mammography has become so sensitive and sophisticated that the technique is detecting "cancers" so early that they may not really become invasive at all? If so, radiologists--by ardently promoting mammographic screening--may well be contributing to unnecessary amputations of women's breasts. I think that all of you should give serious thought to this matter, because I am sure that no radiologist in this country would want to help, inadvertently, cause unnecessary mastectomies.

There is more that I talked about before the Senate, but knowing that Dr. Al Hilberg is scheduled to speak to you, I see no need for me to go into the BEIR Committee Report. So I will end with a plea that you take the woman's point of view into consideration when you formulate the guidelines on mammography. This is, as I said, a plea. However, I must also warn everyone in this room that if radiologists and their radiation-controllers do not set down some rules and regulations--not guidelines and recommendations--that everyone must adhere to as far as equipment and personnel are concerned, there will be such legislation. If radiologists do not police themselves, they will be policed by policemen, whether they come from the State or the national level. Radiologists will have their rights and freedoms, whatever they consider them to be, taken out of their hands by government, because we taxpayers will demand it. Having traveled around the country speaking to women about all aspects of the mammography program, I can tell you that--with no doubt at all--we will not put up with the slipshod and haphazard usage of mammography any longer.

WHO SHOULD HAVE MAMMOGRAPHIC EXAMINATIONS?

Richard G. Lester, M.D.
Department of Radiology
The University of Texas

(**Editor's Note:** This presentation was prepared and edited from the transcripts. The author did not submit a manuscript and declined to furnish the figures cited. We regret the inconvenience to the reader.)

Let me say first that I genuinely appreciate this opportunity of appearing at this Conference of Radiation Control Program Directors. I think that this kind of interchange of information, knowledge, opinion, and fact between radiologists (I am a radiologist) and you all is of particular importance. I think the fact that we are meeting in this fashion, a program co-sponsored by both the American College of Radiology and your organization, is a very forward step. I am particularly honored to be the first of the speakers from the College who will be appearing during the course of the day on the subject.

Let me just say a word about where I am in relation to who I represent, because I guess that is important in this sort of group. I am a radiologist. I am a former director of a Breast Cancer Demonstration Project at my previous location in Durham, North Carolina. I am the chairman of the American College of Radiology's Committee on Mammography and Diseases of the Breast. And I am a faculty member at the University of Texas.

Of course the positions that I am presenting this afternoon represent my own, and it is very hard to identify a particular talk with an entire group. I think most of what I say, however, does represent generally accepted opinion among radiologists and many other physicians interested in breast cancer at this time.

I will present this talk to you in the folowing fashion: First, very briefly to remind you of the extent of the breast cancer problem in this country; secondly, to show you the contribution of mammography by illustration of mammograms and by the sorts of information that can be developed by x-ray examination of the breast; thirdly, as Ms. Kushner has already done, but to reemphasize the importance of understanding the difference between a diagnostic study done for reasons of clinical import, clinical suspicion of cancer on the one hand, and examinations done as a form of survey of public health measure on the other; finally, or next to finally, to discuss the problem of radiation dosage from our perspective as practicing radiologists (I should say my own perspective as a practicing radiologist); and, finally, to present to you what we believe are indications for mammography at the present time.

I would just remind you very briefly, of the dimensions of the breast cancer problem. This is a very large problem in our country. It is not a problem that is internationally the same: for example, instances of breast cancer in Japan are considerably less than in the United States. But in our country, it is the most common cancer among women. These figures are a bit old, and actually some of these numbers are somewhat larger, but, in essence, this is correct, there are an estimated 70,000 new cases of breast cancer per annum. That is to say, 70,000 breast cancers are identified each year in American women. Approximately, at the present time, 7 percent of all females born in the United States will develop breast cancer. That is to say, 7 out of every 100 female live births will, during the course of adulthood, dvelop breast cancer.

As I mentioned, it is considerably more common here than in other countries, and Japan is fairly good as statistics used as an example of this. There are an estimated, now, about 40,000 deaths a year from breast cancer in this country.

These are some of the background statistics that have to be kept in mind in viewing this problem. Secondly, there has been no significant improvement over time in the survival rate, or the case mortality rate in breast cancer. And this is strikingly different than in some other situations.

There has been a striking decrease in mortality rates for carcinoma of uterine, uterus, and cervix since 1930. On the other hand, in breast cancer you see this monotonous plateau at a very high level so that now, unlike 1930, when carcinoma of the cervix was the most common carcinoma in women, now carcinoma of the breast by far is the most common carcinoma in the female population in this country. There has been a sudden upswing in carcinoma of the lung in women in this country, probably related to changes in smoking habits. Of course in men carcinoma of the lung is the most common cancer. It is not in women, but is growing and growing ominously at the present time.

We have to look too, then, to what are the methods for the diagnosis of breast cancer. They are really not very many, and they are really very simple.

Physical examinations; physical examinations sounds neat, and it is neat. But, one; this implies a cancer that has grown large enough to be palpated. Secondly, it implies a patient that has repetitive examinations, or that examines herself. Interestingly, at the present time, most cancers of the breast are found by the woman herself by self-examination of the breast. No program of breast cancer that omits this very important method of teaching women to examine their breasts is a very worthwhile program. It's a particularly important thing for all of us to keep in mind.

Secondly; mammography. And thirdly, another series of methods that may or may not have promise, but at the present time are not suited to the diagnosis of early breast cancer; thermography which, as you know, has been extensively tested in this country and elsewhere. It has some value in the evaluation of larger cancers and the evaluation of patients' preimposed therapy, particularly radiation therapy, but at least in this country the statistical evidence indicates it is not a reliable method today in the diagnosis of pre-clinical breast cancer; that is to say, cancer small enough so that they are, in fact, not palpated by a physician or woman.

This is very much unlike the situation with mammography, where a very sizable number of cancers can be diagnosed before they are palpable. Other methods are, perhaps, of interest. Inparticular, the possibility of using ultrasound radiation instead of ionizing radiation for breast cancer is one that is very attractive and may have promise. There is a fair amount of research going on in this area at the present time. It is an area of hope, but it is not a practical clinical method at the present time for the diagnosis of small, preclinical breast cancers.

Figure 1 lists some of the early workers (interestingly, workers that Ms. Kushner also referred to), and I present this information for you for background. Later on I am going to present more recent information. Keep in mind these are relatively early workers in the field and these represent studies of patients, referred patients; these are clinical patients, not survey patients.

Gershin Cohen in Philadelphia is one of the genuine pioneers in this field and here are his accuracy rates in malignant and benign diseases. In his statistics there is a 12 percent false negative rate; that is to say, cases that were not diagnosed as cancer by Cohen and his colleagues. This is a very respectable clinical rate it should be pointed out. Egan, about 90 percent; Wolfe, about 92 percent; Strack's figures were in somewhat of a different order (this is from a colleague of mine in the early days in clinical practice in a small city in Virginia) in excess of 80 percent accuracy as compared with Gilbertson's report of 70 percent accuracy on the basis of annual physical examination. So, these are some of the background figures that need to be kept in mind.

I thought I would give you a very brief rundown of what mammography is all about. As everyone knows, it is a soft tissue x-ray examination of the breasts. There is nothing injected into the ducts or elsewhere in mammography. There is careful control of both quality of irradiation and of the sorts of films used. The contribution of Egan, originally, and of Wolfe, Martin, and others later on, largely related to the types of films used. Standard film as used for examinations of the abdomen or chest, are not used; as you know, Egan used very slow industrial film, Wolfe used xerographic methods and other types of films, and carefully controlled film/screen combinations have been used subsequently, including the so-called lower dose method; the film/screen combinations by Azarde and others in more recent years.

These are some of the things that we radiologists look for. By far the most important mammographic signs of cancer relate to masses, naturally: very small masses. We look for masses particularly that have spiculated margins, that are circumscribed, or more important, mixed. And, of course, we are particularly interested in seeing masses that cannot be felt on physical examination because the survival rates and, in essence, the cure rates, are directly related to the size of the cancer and to whether it has spread to lymph nodes.

In patients that have no lymph nodes and where the cancers are under no possible lymph nodes, but the cancers are under 2 centimeters, the 5-year survival rates approach 85 percent. In masses under 1 centimeter in transverse diameter, with no lymph node metastasis, the 5-year survival rates now are in excess of 90 percent, whereas the overall 5-year survival rate for all patients diagnosed as having breast cancer is of the order of 50 percent.

This is an enormous improvement with early diagnosis of breast cancer. This is not true for all cancers, but it is true for breast cancer. This is a hopeful cancer and a curable cancer, if it is found in early stages, in very large portions.

So, we are looking for masses, we are looking for special kinds of microcalcifications of the outer mass. These are often associated with the very smallest of carcinomas. We are looking for architectural assymetries, and for certain secondary changes. These tend to be rather later changes; skin and/or nipple thickening, dilated veins and, of course, an enopathy.

I thought I would show you just some of these sorts of things, this is mostly from my own work, and I use xeromammography in my own practice and most, if not all, of my pictures are xeromammograms. This is not to indicate that xeromammography, in my estimation, is a superior method; it is a method of choice, but not the method of choice, in my estimation. As you can see (Fig. 2), there is a sizable mass, spiculation, and retraction. These are some of the signs that one looks for in a carcinoma of the breast.

Figure 3 is a good one to start with simply because it is easy to see. Figure 4 was in the so-called cranio-caudal view or suprainferior view. Figure 5 is the media-lateral, or right-angle view.

Figure 6 a rather small mass. This one was, in fact, not palpated, but might have been. Let me add this one was not palpated, not by some ignorant person, but by a well-qualified surgeon; a friend of mine. To say it could have been palpated is immaterial. It was not palpated. It seems to be a rather small mass, but with some of the same characteristics. This, again, was a malignancy. You can see this is considerably smaller, but it is the same general principle as in figure 5. The previous one was a media-lateral view, and this is a cranio-caudal view. This represents a dominant mass.

Figure 7 is another small cancer. I show this to show a method of localization of these just by placing a needle under focal anesthesia in the breast. There are a number of methods. Some of these tumors are so small they cannot be found very easily at surgery and rather than take out large portions of the breast resulting in a deformity, we are now trying to localize the lesions carefully pre-operatively, so that biopsy can be done with a minimal loss of breast tissue, and a determination made as to whether this is, in fact, a neoplasm or a benign tumor. This was a cancer.

Not all masses are cancers. Figure 8 shows a mass very well marginated, discreet, very modulated, no spiculation. And this was a benign tumor, not a cancer. Not all cancers appear as a mass. Figures 9 and 10 are two films from 1974 and 1975 on the same patient. In Figure 9 there are a number of very tiny calcifications and a very slight change in architecture. At this time, the diagnosis was not made. At this time, we suspected cancer. We were not absolutely certain, but did recommend biopsy. And this was, in fact, a breast cancer.

Figure 10 is a toned down and magnified view of the same thing showing the very subtle change that we were able to identify and recommend biopsy. This is the sort of cancer we want to find, really, because these are the ones with the best prognosis.

Finally, figure 11 is one with more typical malignant calcifications. With this sort of localized change, we would have a high degree of certainty that we were dealing with cancer. This was, in fact, another cancer. And, finally, figure 12 is one from a colleague of mine showing that the same sort of very careful detailed work can be done with the use of film methods; this was from a colleague out here on the West Coast, Dr. Richard Gold. This was biopsied. This mass was so small and so indistinct, you may not be able to see the calcification.

Figure 13 shows one of the techniques that we use in the examination of the specimen at the time of surgery to make certain we are in the right position for a sectioning. On the specimen, you can see a little clustered area of calcification. The tumor is right adjacent to it, actually. But this is the tip-off that we are dealing with a very small neoplasm. Only in the section right adjacent to the calcifications was there a neoplasm, and this was a very early one; no palpable mass, no visible mass on the mammogram, no palpable mass at the time of surgery, but identification of breast cancer by microscopy and no metastatic lymph nodes.

There is no question, then, that mammography can and does contribute to the clinical evaluation of women suspected of breast cancer with a high order of accuracy and in a setting where other methods are not satisfactory. There is no question that mammography makes a contribution to the diagnosis of breast cancer in addition to the contribution of physical examination, and that it makes a contribution in precisely those cases where one would like to make the diagnosis most importantly; namely, an early breast cancer, small size, not palpable in a significant portion of cases, without metastatic disease to the ancillary nodes, with a consequent striking improvement in survival rates.

It is with that background, let me say, that the studies, or the programs, of the American Cancer Society, and then the combined program for the National Cancer Society and the National Cancer Institute, that Ms. Kushner refers to, was developed. I think we need to keep that background in mind. I do not intend here to debate merits of that program, and I must say that I agree with Ms. kushner about some of its failings and limitations, despite the fact that I was a director of one of the 27 centers at one time.

There is no question that they have limitations; and that some of its statistical limitations are important to keep in mind. However, some of the statistical information is particularly important; and I want to present this to you. Before I do, let me just remind you of the age relationship to incidence of breast cancer in this country. There is a very sharp increase in incidence in the age 40 to 45 group. As you know, at the time the BCDDP program was established, it was determined to begin the screening at age 35. I was not a party to this, but I do know some of the reasons that were behind this. One, breast cancer is a tumor that develops slowly, so that it was felt that early diagnosis prior to the time the statistical information, being based on physical examinations, standard diagnosis, would be a benefit. This was the belief. It was believed, despite the fact that it was more recognized that the HIP Study showed no improvement in survivorship under the age of 50, that techniques had improved enough so that such an improvement would be demonstrated. And I will come back to that in a moment.

These are some of the reasons that the protagonists of this program used for choosing this cutoff period, 35, although the statistics showed the striking increase at the age 40 to 45. Let me point out that the incidence actually starts to drop off slightly although it is monotonous, really, beyond the age of 50. This group, at least in my own personal estimation, age 40 to 50, is an especially important group for the early diagnosis of preclinical breast cancer. And that is the point that the protagonists of the BCDDP programs were trying to establish.

Let us look at some of the statistics. These statistics are not the latest, and more recent statistics may be presented by one of the other speakers. These statistics were provided to me by Dr. Diane Fink last October.

At that time there had been roughly 272,000 women screened in that program. There had been a little over 10,000 biopsies recommended, and 5,500 biopsies, on which there was information. There may have been more biopsies performed as of that moment, but this is the statistical data that was available at that time. Of those biopsies performed, roughly 5,000, there were 952 pathologically confirmed cancers. These statistics, I think, are clear; about one out of five biopsies turned out to be cancer. Of those, there were 901 patients for whom full statistical reports were available.

Let me emphasize once again that the greater contribution to this is in the period 40 to 49. But my statistics relate to the whole group, 35 to 49. Of all the patients in the program, let me say, roughly half at that time, were patients over the age of 50, and half were under the age of 50. Of the patients under the age of 50, 246 cancers were found of the total of 901. These figures are based on this figure when the modality reports were available. So, roughly one-quarter of all of the cancers in the BCDDP program diagnosed at the time (last October), were in the 50 percent of women under the age of 50. This is a very sizable proportion of breast cancers. Furthermore, in these women, in 118 cases, both physical examination and mammography, demonstrated the cancer. That is to say, it was a palpable mass, and there was x-ray evidence of breast cancer; 118 women.

In 22 women, the physical examination was positive and the mammogram was negative. And this is something that must be kept in mind; mammography is not 100 percent reliable. But in 106 of these women the mammogram was positive and the physical examination negative. Combining this figure, 106, and this figure, 118, the accuracy of mammography in this group of women (not a pure screening let me point out, but nonetheless a group of women different than the usual referred patient), was 91 percent. The accuracy for physical examination, on the other hand (that is to say, the 118 figure, where both positive and the 22 figure, where the physical examination only was positive), is under 50 percent. This is in a series of early cancers; the axilliary metastisis rate, which is a monotonous, roughly 50 percent in routine patients, was under 25 percent in these women. So, this is a striking improvement, we believe, and impressive figures.

Now, there is another side to this, of course, and that is the issue of radiation. I want to present to you the calculation that Dr. Bross has presented, which is a calculation that must be considered in any study of the mammography problem. It is a quite clear that if mammography does not contribute, then the most minute dose of radiation is unnecessary, meddlesome, and undesirable, because there are at least theoretical considerations to believe that even small doses of radiation may cause breast cancer in a very small number of patients. There is no direct evidence of this, as you know, but the evidence from the fluoroscopy study, involving many hundreds of roentgens, in some cases over a thousand roentgens, the study of the mastitis patients involving several hundred and others, do demonstrate the presence of breast cancer. If one extrapolates this as Dr. Bross does, down to a zero level, then one can believe that even very small quantities of radiation can cause breast cancer in very small quantities of women. The calculation is as follows: If one extrapolates to zero, the figure that he uses for cases of breast cancer per million rad's per year is 6; you take the number of patients examined, the average radiation delivered (and we emphasize average radiation delivered), and the additional life expectancy, divide that by a million, and one can calculate cancers induced.

Well, is this correct? I don't know. But must this be considered? Of course it must; and we must keep this in mind that this does need to be considered. Let me point out, however, that any reduction in radiation delivered in this formula Dr. Bross's formula (this is the worst possible case), while maintaining accuracy will result in a direct arithmetic improvement in the situation; that is to say, a direct decrease in the number of cancers theoretically induced.

Consequently, we and you have been devoting a very substantial amount of effort to the reduction of radiation while maintaining diagnostic accuracy in this area. And there are so many contributions to this that I am almost embarrassed to single any out. But I would like to single out three that I believe are particularly important.

One; the Bicehouse Report was quite a shocker to me and to many other radiologists. The notion that some of our colleagues that we all knew (it wasn't any of us; I knew that, because I have been measuring my radiation doses right along), were inadvertently delivering quantities of radiation that Mr. Bicehouse reported, was very disturbing and, I think, had a very salutary effect on practicing radiologists around the country.

Secondly, the BENT program, developed by the Bureau in recent years, has demonstrated to my colleagues around the country the advantages of measuring radiation, the simple steps that can be taken to correct excessive radiation, and the opportunity that does exist to preserve diagnostic accuracy while using more radiation doses.

Thirdly, and my own contribution through the Committee, has been the educational programs and the colleges carried forward now in the area of breast conferences now and other areas including mailings and so on to emphasize the importance of reducing radiation dosage while preserving diagnostic accuracy and methods for doing this. This has been reported at many conferences and I believe has had a salutary effect.

Recently, we conducted a survey of radiologists around the country. And of 600 and some odd radiologists that responded to the survey, who were measuring radiation dosage, in excess of 80 percent of the radiologists reporting were using a calculated dose at the skin of 2 rad's or less.

I might go rapidly through some of the other kinds of public relations that were rather different from those Ms. Kushner mentioned. This is a first of three; this looks pretty reasonable: "Experts Discuss Use of X-Rays and Relation to Breast Cancer," and it looks pretty nice. That newspaper headline comes from Montgomery, I think, but illustrates, I believe, the rather extraordinary negative publicity that has, in fact, kept women who should be getting breast cancer from having those examinations. This headline and others are rather widely distributed; San Francisco, Alabama, Toronto, Ontario. The man who predicted the breast cancer epidemic, for which I think there is really no evidence, is the same Dr. Bross with the calulations, as a matter of fact.

But let us look at some dosages in various places (Fig. 14). My own figures are from a year ago and are air exposures in this particular case. I have listed the method that I was using at that time, the tube and so on, because I think one has to know exactly what one is talking about; this is reality, not guesswork. This is when I was in North Carolina using my exposure to the breast cancer project at that time. Air exposure 1.4 R, with one view, 1.8 R with a media-lateral view, one can add about 20 percent to this to arrive at a rad dose to the skin.

Much more importantly, we should multiply by 20 percent in order to arrive at a midline dose, which is the dose, of course, that Dr. Baillar and Dr. Bross and other critics of mammography are talking about. So that at this time, the total exposure at the breast surface was somewhat in excess of 2 rad's, and the mid-line dose at about 0.5 rad for a two-film examination. At the same time in my other office, if you will, at Duke Medical Center, I was getting this sort of exposure with a rather different system. This was a beryllium window tube, and this one more inherent filtration but without added filtration.

Here I have added a 0.5 mm aluminum to the beryllium window here, no added filtration, but there was so much inherent filtration and rather similar dosages. Here are some that I collected from a variety of colleagues. I am not going to identify them by name, but as you can see, these are various methods; the xerox method, using my own figures, but at a slightly different time, as you can see, with two different systems. I guess this is after I moved to Texas. And my midplane exposure (I use a 25 percent calculation) was less than 1 rad with one system and less than that with another system. This is with the use of the so-called lo-dose 1 of film/screen method of DuPont and 0.75 rad total; the two-exposure examination, the standard examination, not the 2 rads that Dr. Baillar originally calculated, but less than half of that; 0.75 rads.

Here's another system--two other systems, actually, with similar figures. The so called minar system of Kodak and the low-dose 2 systems of DuPont that at that time was in another physician's hands, with a dose of approximately 4 rad midline for two exposures. He has one for use of the 3M trimax Rare Earth System, a very low dose, but this is a more experimental system, I should add, and there is some question about its reliability as compared with some of the others.

Here is still another. It is from another colleague of mine who had added more filtration than I was using. Please note with the positive mode, less than 0.5 a rad; with the negative mode with 2 mm of aluminum added, still less radiation.

I thought I would present my own current figures to you in the next three figures; this is the real world, not theoretical considerations. This is what I am doing in my department in Herman Hospital, University of Texas Health Science Center, Houston, Texas, right now. We are using the Siemen's Man-O-Mat unit. We are using a tungsten tube with a beryllium window; it is a three-phase system. We have added 2 mm of aluminum. We use xeroradiography as our image receptor system.

Here are actual measurements made by my colleague, Dr. Heathersy, a physicist, about 2 or 3 months ago. We used 42 kVp; our standard is about 44 kVp, but we made three measurements at 42, 44, and 46 kVp for different size breasts. This is in millirads now, and I draw your attention particularly to the estimated midline dose in rads, roughly 0.2 rads, the midline, for a two-film examination of the breast as compared with the 2.0 estimated figure when Dr. Baillar wrote his paper. You see, there has been a sizable reduction in radiation dosage. Efforts along these lines need to be continued; efforts are continuing along these lines.

I think there does need to be policing of us, but I think it needs to be policing as is being done now. I think that the quantity and quality of the response that you have made to us and we have made to you in this situation demonstrates that the sort of voluntary efforts we are going through now is an effective one.

But what are the indications from mammography? That is what I was asked to talk about. I think there are two sets; one, one must keep in mind that there is a difference between clinical patients and survey patients. In the clinical category, we believe that some of the major indications for mammography are listed in figure ___. We believe, too, that these are indications of high-risk category. I do not intend here to attempt to prescribe a precise age for originating mammography. I think that is impossible at the present state of our knowledge. Nor do I intend to attempt to prescribe a precise time interval for mammography. I do not think that is possible in all settings, but I do believe that these are some of the indications for the performance of mammography in the absence of specific complaints. Obviously, patients who have had breast cancer themselves are in a very high risk category compared to the usual. Such patients should have regular periodic mammography, in my estimation, even in the absence of complaints in the opposite breast. Patients with a family history of breast cancer, particularly in the first level of relatives, mother and sister, should have periodic mammographies. Patients with significant findings on baseline studies--I do not want to go into this in detail, but let me say in recent years it appears to be some genuine evidence that there are indicators on the mammogram itself of high risk populations; and these patients should be more carefully followed.

Patients who have not delivered children and who are in the cancer age group are at a higher risk for breast cancer than patients who have had children early in life. So, there is low or late parity as well as no parity at all, or indicators of relative high risk. Patients who had early onset of menstrual periods. Older patients; I will not put a specific age to this, but I think the statistics that I showed to you are very demonstrative in this regard. The risk is increased with age after 40 years, so that in my own practice I advise baseline mammography sometime around this period in life, and periodic examination after that, based on other risk factors. I recommend to my patients, annual or other, regular mammography. There is no magic to exactly 1 year over the age of 50. And then these are more modern and more controversial indications.

I think the hypothyroidism is probably not correct. There is a lot of argument about this, and there appears perhaps to be some relationship to diabetes and regional carcinoma, but these are less reliable indicators, in my estimation, than others. There will be more talk about this in much greater detail in one of the later talks. But these are some of the clinical indications that I use in my own practice in evaluating patients.

In summary, what I have tried to present to you very briefly, is the background of the breast cancer problem; a national, important problem in cancer; and some of the opportunities of, the uses of, and the statistics about mammography itself so that the efforts that are being made to reduce dosage while preserving diagnostic accuracy and some of the indications that I use in my own practice for advising women to have x-ray examinations of the breast.

Once again, I would like to say I really appreciate the opportunity of being here and I look forward to the remainder of the session.

NATIONAL CANCER INSTITUTE'S GUIDELINES FOR MAMMOGRAPHY

Winfred F. Malone, Ph.D.
National Cancer Institute

Breast cancer is the leading cause of cancer death among women today. In 1977, an estimated 90,000 new cases of breast cancer will be diagnosed in women and 34,000 deaths will occur. It is the leading cause of death among women 40-44 years of age and the second leading cause of death for women in other age groups (1). At the present rate, 1 out of every 15 American women will develop breast cancer at some time.

The purpose of this paper is to discuss briefly the current breast cancer screening guidelines of the National Cancer Institute and to report to you some of the preliminary detection and monitoring data that is now available from the Breast Cancer Detection Demonstration Projects (BCDDP).

The purpose of the Breast Cancer Detection Demonstration Projects is to demonstrate the ability to recruit, screen, and follow a population of 270,000 asymptomatic women for the early detection of breast cancer. Screening procedures include history, physical exam, mammography, and thermography in all women. The original purpose of recruitment and initial evaluation has been accomplished and has resulted in the detection of many breast cancers.

In 1973, 27 such screening centers were established throughout the United States. Each of these 27 breast cancer detection centers was to enroll 10,000 asymptomatic women in its program, making a national total of 270,000 screenees. Screening methods include: personal history, physical examination, mammography, and thermography. After the initial screening procedure, each woman was asked to return for 4 more examinations at yearly intervals. After the 5 annual screening examinations, the 270,000 women were to be followed up for an additional 5 years so that survival rates can be determined. See table 1 for the total cancers found in the initial, 2nd, and 3rd annual screenings conducted at the Centers.

Table 1. Total cancers found[a]

Screening Series[b]	Number of Cancers	Number of Screenees
Initial	1,269	262,848
2nd Annual	271	128,202
3rd Annual	57	22,559
Subtotal	1,597	
Interval Cancers	236	
Total	1,833	262,848

[a] through June, 1976, for initial visits through March
[b] includes early recalls for each series

As presented in table 1, by the end of June 1976, 262,848 women had been screened; and within this group, 1,833 cases of breast cancer were discovered. Eighty-seven percent, or 1,597 cancers, were found during the screening procedure itself, and 13 percent, or 236 cases, were interval cancers, or neoplasms found during the period between screenings.

The initial screen was by far the most valuable in terms of number of cancers detected and subsequent screenings resulted in fewer cancers detected.

Table 2 presents data on total cancers detected according to history or symptoms. This includes information on the numbers of women with a previous history of cancer, those with overt symptoms, and those in the asymptomatic or symptom-free category. Twelve-hundred thirty cases, or 67 percent of the cancers, were detected in women without previous symptoms; 516, or 28 percent, were detected in women with overt symptoms; and 87 cases, or 5 percent, in women with a previous history of cancer. This, again, comes to a total of 1,833 cases in the total screened population of 262,848.

Table 2. Total cancers by history or symptoms

Screening Series	Previous History Of Cancer	Overt Symptoms[a]	Asymptomatic
Initial	62	329	878
2nd Annual	10	81	180
3rd Annual	3	20	34
Subtotal	75	430	1,092
Interval Cancers	12	86	138
Total	87	516	1,230
Population Base	2,472	38,221	222,155

[a] Includes: presence of lumps, discharge and any previous breast surgery except for malignancy.

Table 3 presents information on the total cancers detected by 5-year age groups. In the age group 35-49, 613 cases, or 33 percent, were found. Of these, 501, or 31 percent, were detected during the screening, and 112, or 47 percent, were found during the interval period. I might also point out that 135,073 women, or 51 percent of the screenees, were in this 35-49 year old age group.

Table 3. Total cancers by 5-year age group

Age	Detected at Screening	Interval	Screenees
35-39	59	28	41,111
40-44	151	30	45,365
45-49	291	54	48,597
50-54	307	46	46,179
55-59	289	35	33,959
60-64	228	24	22,797
65-69	153	11	14,513
70-74	80	3	6,189
Other	39	5	4,138
	1,597	236	262,848

The data closely approximate the estimates of the Third National Cancer Survey indicated that nearly 1/3 of all breast cancers occurred in women below the age of 50 (2).

In the 50-74 year old age group, there was a total of 1,220 cases, or 67 percent, of the total cancers. One-thousand ninety-six cases, or 69 percent, were detected during the screening, and 124, or 53 percent, were interval cancers, or those found during the interval between the screening periods.

In table 4 data are presented on the total cancers detected by age group, history, and symptoms according to various modalities including physical exam and mammography. In the 35-49 year age group, 199 cases, or 40 percent of the cancers, were detected by mammography alone. In the 50-74 year old age group, 504 cases, or 48 percent, of the cancers were detected by mammography alone. Thus, 40 percent of the cancers in the 35-49 age group were detected by mammography alone and only 10 percent by physical exam alone. In the HIP study, the percentage of cancers detected by mammography alone was 33.3, and the percent of cancers detected by mammography alone in the age group 40-49 was only 19.9.

Table 4. Total detected cancers by age group, history and symptoms

Status	35-49			50-74			Other		
History of Breast Cancer	15[a]	4[b]	1[c]	58[a]	32[b]	2[c]	2[a]	1[b]	0[c]
Overt Symptoms	164	59	23	248	76	23	18	2	1
Asymptomatic	322	136	27	751	369	35	19	5	2
Totals	501	199	51	1,057	504	60	39	8	3

[a] all modalities
[b] mammography alone
[c] physical exam alone

Table 5 presents information on the nodal status of the cancers detected according to various age groups. Sixty-nine percent of the cancers in the 35-49 year old age group were in situ or invasive, 0 nodes category, and for the 50-75 age group, 68 percent of the cancers were in the first 2 categories of the table. Thus, in both age groups nearly 70 percent of breast cancers were detected in an early stage, before they had spread to regional lymph nodes in the axilla. It follows that these patients have a much improved survival rate.

I must caution that the number of cancers detected does not directly measure the benefits of screening. The most important end point for evaluation of screening programs is the overall reduction in the number of deaths from breast cancer. Such factors as what would be the survival in the absence of screening, the number of deaths that occur despite early detection, and consideration of biases in the data such as self-selection of screenees must be considered.

Table 5. Type of cancer by age group

Cancer Type	35-49	50-74	Other
In Situ	162	250	7
Invasive, 0 Nodes	184	473	16
Invasive, 1-3 Nodes	63	117	6
Invasive, 4+ Nodes	27	75	5
Invasive, Nodes Unspecified[a]	28	76	4
Invasive, Nodes Unspecified[b]	19	39	0
Unknown Type	18	27	1
Total	501	1,057	39

[a] with less than radical mastectomy
[b] with radical mastectomy

I would like to turn to a discussion of risks, and a most important factor is the dose or exposure to radiation. In order to carry out a radiation monitoring program, the Division of Cancer Control and Rehabilitation (DCCR), National Cancer Institute, established 6 Centers for Radiological Physics (CRP's). Each CRP has been assigned an area in which it is to provide services and a designation indicating the area which it serves.

Each CRP operates under an individual contract with a leading university or Cancer Center. Since there was a need for a mechanism to ensure national uniformity in the nature and quality of services provided by each of the Centers, and a need to provide a means for communication between all Centers and DCCR, a coordination program was established. This coordination program is provided by the American Association of Physicists in Medicine (AAPM). In the next few paragraphs I would like to describe the radiation physics program that the CRP's have undertaken on the BCDDP program.

The primary aim of mammography is to obtain the maximum medical information while subjecting the patient to minimum radiation risk. Mammography is a high local dose procedure because of the low filtration and high tube current employed. The achievement of optimal information with minimum exposure requires: (a) assurance that all equipment is functioning properly; (2) operation by equipment is only by competent personnel; and (3) technical factors that will minimize exposure be selected.

There are many complex, interrelated factors that determine the radiation exposure received by the patient and the diagnostic information contained in the x-ray image viewed by the radiologist. Many of these factors act in such a way that a reduction in patient exposure may cause a reduction in radiographic image quality. Thus, we are seeking a combination of factors that will minimize the radiation exposure to the patient and, at the same time, produce an x-ray image that provides an accurate diagnosis. The optimum combination varies greatly for different types of image systems and for different types of x-ray generating equipment and also patient dimensions.

The visualization of normal structures and signs of disease within the breast is difficult and requires a very special type of x-ray examination; in particular, the x-ray beam must be of a lower average energy (less penetrating) than x rays used for examining other parts of the body. This necessary reduction in x-ray penetration means that a relatively greater amount of x-ray energy is absorbed within the tissue.

The six Centers for Radiological Physics have recently completed a third year review of mammographic radiation exposures in the screening centers participating in the Breast Cancer Detection Demonstration Project. A nationally uniform protocol of measurement was jointly developed, tested, and followed. The equipment utilized was intercompared and calibrated to give uniform results. Their report is a detailed analysis of the nationwide compiled data. Correlations of exposure with radiographic parameters like receptor type, type of equipment, and the target-filter combination have been evaluated.

The measurements were made with ionization chambers uniquely suited to mammographic measurements. These chambers were specifically designed to have an energy independent response to within plus or minus 1 percent for x-ray qualities used in mammography. All the chambers used in these measurements were calibrated in a facility having standards traceable to the National Bureau of Standards. Each step of the protocol for the measurements was tested and the chambers were intercompared with one another on mammography equipment prior to measurement methods throughout the country. The ion chamber measurements are being supplemented by measurements using thermoluminescent dosimeters on Lucite phantoms at the surface of the breast. This technique is being used for periodic followup (4).

In year 3, up to the end of March 1977, data was reported on 47 mammography systems. Of these, 33 machines, or 70 percent, were Xerox. Fourteen machines, or 29 percent, employed film/screen combinations. In year 2, the CRP's reported on 63 mammographic systems; of these, 44 (70 percent) were Xerox; 14 (22 percent) used film/screen; 5, or less than 7 percent, employed film without intensifying screens (3).

Figure 1 shows the distribution of exposures that were found at the BCDDP projects in the 1st and 3rd years. The values are reported in roentgens at the surface of the breast per image. Backscatter is included in these values. The average value for all units during the 1st year was 3.1 R. Initially, there was a rather wide spectrum of exposures. Results of the 3rd survey indicate that the dose had been reduced to 1.2 R; thus a 61 percent overall decline in exposures from the 1st year.

With regard to Xerox equipment, there are 33 units, or 70 percent of the equipment, in the program. In figure 2 it can be seen that the averge exposure was 3.2 R in the 1st year of monitoring. This declined to 1.4 R in the 3rd year. This resulted in an overall drop of 56 percent in exposures from the 1st year.

These decreases in surface exposure for Xerox equipment were undoubtedly due to increases in kVp and filtration. Along with these changes there was a shift from Mo-Al filter combinations to tungsten-aluminum filter combinations which also permitted decreased surface exposures. While there has been a 56 percent reduction in exposure for Xerox equipment, there has not been the corresponding decrease in absorbed dose. Shrivastava has reported that dose retained for Xerox is by no means proportional to surface exposure (5).

In figure 3, information is presented on exposures from film/screen combinations. There are 14 of these various units in use in the program. During the 1st year the average exposure was 1.5 R. This is down in the latest survey to 0.6 R/view, or a 60 percent change. The average exposure in the non-screen film system was 7 R in the first year. There were none of these units included in the latest report.

Although measurement of radiation surface exposure is important, knowledge of radiation absorbed dose at a depth within the breast is necessary if estimates of radiation carcinogenesis are to be applied to mammography. Because of this relation to risk, radiation dose rather than exposure should be employed when making comparisons between techniques and image receptors.

Each of the BCDDP Centers is being monitored on a bi-weekly basis using TLD's. These thermoluminescent dosimeters (TLD's) are exposed and the readings obtained from these dosimeters serve as a baseline measurement for the weekly monitoring of exposure rates from the unit as carried out by mailed TLD's. Each week the CRP's mail out 1 or more cards carrying several TLD's to each BCDDP Project in its region. These cards are positioned on a plastic phantom, and exposed by the x-ray technologist at the project as per instructions provided by the CRP's. The TLD's are mailed back to the physics centers where they are "read out." The exposure indicated by the TLD is compared with that of previously exposed TLD's.

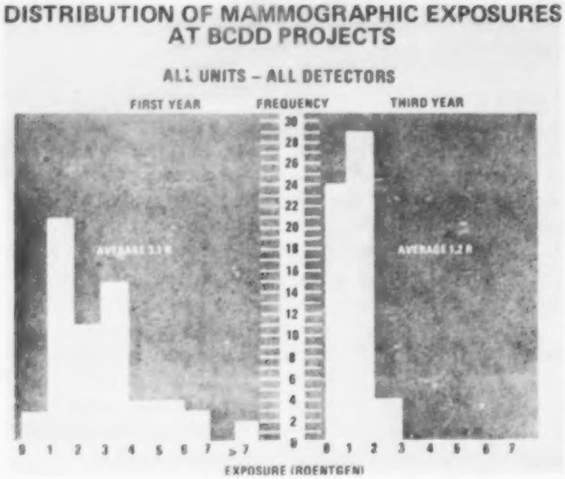


Figure 1

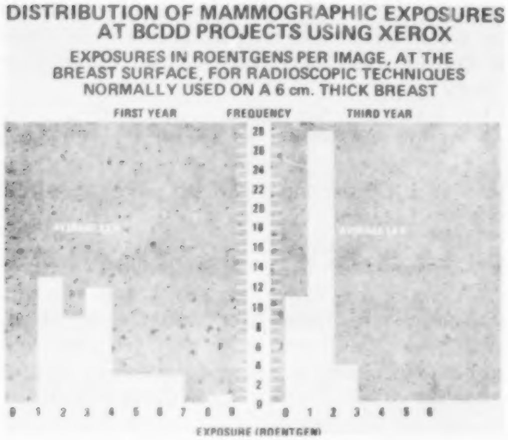


Figure 2

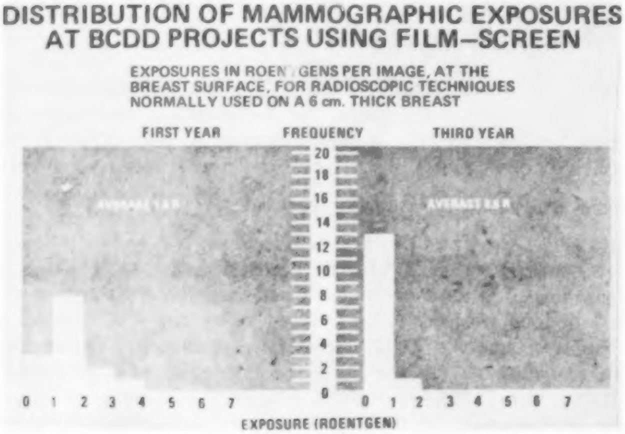


Figure 3

If the TLD indicates a marked change in exposure, the BCDD Project is notified of the change and inquiries are made in an attempt to identify the problem. If the problem cannot be identified, and a following TLD check indicates a problem still exists, CRP personnel re-visit the Project.

If the Centers agree, TLD dosimeters are also placed on the breast of some patients during mammography to monitor actual patient exposure. At those Projects where this is being done, the normal procedure is to choose 5 patients at random each week and irradiate the TLD during 1 mammographic exposure.

Through an interagency agreement with the Food and Drug Administration, the BENT Program has been developed. Breast Exposure: Nationwide Trends (BENT) is a voluntary mammography quality assurance program conducted by State radiation control agencies with the active involvement and cooperation of State and local medical and radiological societies. The Bureau of Radiological Health, FDA, is providing the States with dosimetry and equipment support as well as training and technical assistance during the conduct of the program. The agreement became effective beginning November 1, 1976, and it is the goal of the Bureau to support all State radiation control agencies in the implementation of the BENT Program by September 30, 1978.

BENT measures mammographic exposures through the mailing of thermoluminescent dosimeters and advises radiologists of the exposure at their facility in relation to the exposure to other facilities using similar image receptors. Subsequent identification and correction of problems at facilities where the exposure appears unnecessarily high or unusually low results in a reduction in unproductive radiation exposure and improved image quality. Changes in mammographic techniques and exposures are then assessed by remailing TLD's to all mammography facilities.

To date, the 5 pilot States have gathered exposure data on over 400 mammography facilities. These facilities are estimated by the States to represent more than 95 percent of the mammography facilities in their jurisdictions. The mean exposures for different categories of image receptor are listed below. Individual exposures ranged from 0.025 roentgens (R) to 16.6 R for a single craniocaudal exposure. About 80 percent of the exposures were less than 2 R (6).

Eighteen States are currently in some phase of the program and additional States are being scheduled. It is anticipated that 40 percent of the States will be involved by November 1, 1977. BENT uses TLD measurements to advise radiologists of the mammography exposure at their facility in relation to the exposure at other facilities using similar image receptors. Subsequent identification and correction of problems at facilities where the exposure appears unnecessarily high or unusually low results in a reduction in unproductive radiation exposure and improved image quality.

Along with the development of monitoring programs and our overall concern about the risks and benefits in mammography, the National Cancer Institute initiated in October 1975 an ongoing review of the use of x-ray mammography for women under 50 in October 1975. Three committees were established at the request of the Director, NCI. One group, headed by Dr. Lester Breslow, Dean of the School of Public Health, UCLA, was to estimate the gross and net benefits of adding mammography to history and physical examination in the HIP breast cancer screening project. Dr. Breslow presented the findings of his group in a meeting held July 19, 1976, at NCI. The meeting was attended by directors of the 27 breast cancer detection centers and representatives of the NCI, ACS, American College of Radiology, and the FDA's Bureau of Radiological Health. The Breslow report recommended that, based on their review of the HIP study, routine mammographic screening in women less than 50 years of age be discontinued; the amount of radiation in mammography for women of all ages be standardized at the lowest level possible that preserves diagnostic quality; and additional randomized clinical trials involving women under 50 be carried out to more clearly define the value of mammography in relation to other means of detecting breast cancer (7). Dr. Louis Thomas, a pathologist at the NCI, was asked to review the pathology data from the HIP study. Dr. Arthur Upton, Dean of Basic Health Sciences, Health Sciences Center, State University of New York at Stony Brook, was asked to lead a group evaluating the relation between the benefit and risk in mammographic screening for the detection of breast cancer.

Upton provided an interim report, and is quoted as follows: "The possible risk of inducing a breast neoplasm by the mammographic procedure itself is assumed, but for any individual women is very small," . . . "a single mammographic examination with the newer low-dose technique, which involves a dose of 1 rad or less, would be expected to increase a woman's lifetime risk by no more than 1 percent. Hence, since the risk from natural causes that the average woman will develop breast cancer during her lifetime is roughly 1 in 15, or 7 percent, a single mammographic examination might increase her lifetime risk from 0.07 to 0.0707; by the same token, it would take 100 examinations to double her lifetime risk--that is, to raise it to 0.14. Because the incremental risk per examination is small relative to the individual's lifetime risk from natural causes, a woman should not be reluctant to have a mammogram if there are medical or psychological grounds for desiring the information it could provide. On the other hand, although the presumptive risk to a single individual may be small, the total risk to a large population of healthy women might not be justified unless outweighed by the expectation of a commensurate benefit (8)."

Based on these recommendations, the National Cancer Institute on August 26, 1976, sent interim guidelines to all 27 Breast Cancer Screening Centers. These interim guidelines were to be in effect until all of the final reports have been reviewed by the Director and NCI's own review of the problem has been completed. I quote from the guidelines as follows:

> "We cannot recommend the routine use of mammography in screening asymptomatic women ages 35-50 years in the NCI/ACS BCDDP at this time. However, in the face of a very small presumed risk for any individual woman, we do not recommend withholding mammography from a woman age 35-50 years if she and the physician agree that it is in her best immediate interest (9)."

For asymptomatic women over 50 years, mammography is indicated as part of the regular screening program. For women of any age in which there is a suspected breast neoplasm, mammography is an accepted part of the complete diagnostic workup.

The final reports of the three expert groups have now been received and they have recommended that "routine screening of women under 50 years of age be discontinued." In addition, the Cancer Control Advisory Committee recommended on May 3 that screening with mammography in the 35-49 age group specifically be limited to women in 2 situations (10).

While the August guidelines did not recommend routine use of mammography for women under 50, they also did not recommend withholding mammography if a woman under 50 and her physician agreed it was in her best interest based upon an interpretation of possible risk factors. But the changes, which became effective in May 1977, end routine use of mammography in screening women age 35 through 49 except for the following 2 situations in which the benefits are believed to outweigh the small risks involved:

1. A personal history of breast cancer; or
2. A history of breast cancer in the screenee's immediate family (mother/sister) (11).

I want to emphasize that these modifications are based upon (1) joint recommendation of three ad hoc expert groups, (2) on the advice of the Cancer Control Advisory Committee, and (3) on a review of the use of mammography within the projects since the August guidelines were issued. The 27 project directors of the Centers participating in the screening demonstration have also concurred with the changes.

The Director of the National Institutes of Health will conduct a breast cancer screening consensus meeting in early September 1977 to assess all data on the benefits and risks of breast cancer screening, including mammography. This meeting will determine future NCI activities regarding mammography. It will be held after the Institute receives a report of a fourth working group, now assessing data collected within the current breast cancer screening project. The reports of the other three expert groups were based primarily on reviews of a study conducted in the 1960's by the Health Insurance Plan of Greater New York. The findings and recommendations of all four groups will be considered at the consensus meeting.

In summary, breast cancer is the leading cause of cancer death among women today. At the present time, 1 out of 15 American women will develop breast cancer at some time. The American Cancer Society and the National Cancer Institute have established 27 Breast Cancer Detection Demonstration Centers to screen and follow 270,000 women by history, physical examination, mammography, and thermography. The present interim guidelines with regard to breast cancer screening have been enumerated together with preliminary data from 3 years of detection and radiation exposure monitoring. During the first 3 years, some 1,833 cancers have been discovered. There was an approximately 61 percent reduction in radiation exposure during the past 3 years.

The National Cancer Institute has entered into an agreement with the Bureau of Radiological Health (FDA) for the development of radiation control programs in mammography at the State and local level. The application of ionizing radiation to large segments of the population must be made with caution since the magnitude of the effects are difficult to quantify and remain largely unknown.

REFERENCES

1. American Cancer Society, Cancer Facts and Figures. New York, N.Y., 1977.

2. Third National Survey; Incidence Data, National Cancer Institute Monograph 41, Bethesda, Md. March 1975.

3. Malone, W.F. Radiation Exposures and Dose Reduction in BCDDP, Unpublished Report. July 1976.

4. DeWerd, L.A. and Wochos, J.F. Symposium on Physics of Mammography, Mideast Center for Radiological Physics, Madison, Wisconsin, March 1977.

5. Shrivastava, P.N. Possibilities for Dose Reduction in Radiographic Breast Screening. SPIE Optical Instrumentation in Medicine 96:430-434 (1976).

6. Jans, R. Semi-annual Report, Interagency Agreement November 1, 1976, to April 30, 1977, FDA, June 1977.

7. Breslow, L. Report of NCI Ad-Hoc Working Group on Estimating the Gross and Net Benefits of Adding Mammography to History and Physical Examination in the HIP Breast Cancer Screening Project, July 15, 1976.

8. Upton, A.C., et al. Risks in Mammography, July 8, 1976.

9. Fink, D. Letter of Screening Guidelines to Breast Cancer Center Directors, August 1976.

10. Breslow, L. Final Report of the National Cancer Institute Ad-Hoc Working Group on Mammography Screening for Breast Cancer, DHEW Pub. NIH-77-1400, March 1976.

11. Modification #1, Operational Memorandum #6, Breast Cancer Detection Demonstration Project, National Cancer Institute, May 3, 1977.

RISK FACTORS TO CONSIDER IN SURVEYING ASYMPTOMATIC WOMEN

Albert W. Hilberg, M.D.
Division of Medical Sciences
National Research Council
National Academy of Sciences

Breast cancer is one of the more common types of malignancy in women. There also seems to be increase in breast cancer occurring in men. Perhaps as many as 1 woman in 16 or 1 woman in 13, depending upon the statistical studies cited, will develop carcinoma of the breast. The earlier the diagnosis of breast cancer can be made, the better the prognosis may be.

There are some general risk factors that should be considered:

1. A history of breast cancer in either mother or sister;
2. A long menstrual life - The early beginning of menses and late cessation seems to be more predominant in breast cancer cases;
3. The age of the individual and race play a role. Breast cancer more often occurs after age 50 and appears to be more predominant in white females and certainly less predominant in oriental females;
4. Early pregnancy, before age 25, seems to have a definite protective role against development of breast cancer;
5. Socioeconomic status, the higher the status, the more likelihood of developing breast cancer;
6. Nursing seems to have little effect on the development of breast cancer in the U.S., contrary to earlier views on this matter;
7. The general endocrine milieu of the individual appears to be important. If there are other indications of endocrine imbalance, the likelihood of breast cancer seems to be increased;
8. The presence of an atypical hyperplasia as diagnosed by excisional or needle biopsy or by the palpation of a gritty feeling in breast tissue in important;
9. The presence of cancer in one breast, even though successfully treated, leads to a higher incidence of the presence of cancer in the other breast. Whether this is a primary cancer or a metastic cancer remains somewhat a controversial point.

Cancer of the breast is a systemic disease from its inception. It is usually multifocal and often bilateral. Breast cancer always seeks vascular channels, either lymphatic or blood vessels. Thus, breast cancer must be treated even in its early stages as a systemic or generalized disease.

We can, from just the brief listing given, understand the concern and the need for early diagnosis of cancer of the breast. Mammography of the breast seems to offer just such a benefit of early diagnosis. Radiographic studies of the breast can reveal lesions in breast tissue that may or may not be palpable. Mammography can also be helpful in localizing the breast lesions for further diagnostic work-up. Whether mammography presents an excellent screening technique for the early diagnosis of breast cancer in millions of women has become a very controversial issue.

The controversy primarily centers on the risks of induction of breast cancer by exposing the breast to ionizing radiation in relatively small amounts, although the amount of exposure is in itself a controversial issue. The amount of exposure has been reported as high as 45 rads per mammographic examination. The exposure ideally is much less and, in most instances, has not exceeded 2 to 4 rads per examination.

Just what magnitude of risk may be associated with this level of exposure to ionizing radiation can be estimated only by extrapolation of probable breast cancer induction from considerably higher doses of ionizing radiation used either for therapy of some other disease, for diagnostic procedures not associated with breast cancer, or in the instance of atomic bomb survivors incidental or accidental exposure to a single high level of ionizing radiation. In addition, the magnitude of risk is usually expressed in numbers that are calculated based upon a linear hypothesis of effects of ionizing radiation. Adding to the confounding of the problem is the relatively long latent period between exposure and development of breast carcinoma which may be from 15 to 25 years.

If all of these caveats are kept in mind, then calculations of risk per rad exposure to breast tissue may be judged accordingly.

The evidence of a risk of radiation induced breast cancer results from primarily 3 epidemiological studies:

1. Women who had multiple fluoroscopic examinations of the chest in the treatment of pulmonary tuberculosis;

2. women who received x-ray treatment for post-partum mastitis; and

3. women exposed to the atomic bomb in Hiroshima and Nagasaki.

These studies and the problem of estimating risk of breast cancer from exposure to ionizing radiation were reviewed most recently by Upton et al., in the publication of March 1977, entitled, "Final Reports of National Cancer Institute Ad Hoc Working Groups on Mammography Screening for Breast Cancer and a Summary Report of Their Joint Findings and Recommendations." (1)

Briefly, Upton and his group reported that in the fluoroscopy studies, based upon a mean cumulative dose to the breast calculated to approximately 1,215 rads and the assumption of a linear hypothesis of effect, the risk during the 11th to the 28th year of followup "corresponds to approximately 8.5 cases of breast cancer (or 3.8 cancer deaths) per 10^6 person-years per rad to both breasts."

They indicate that there is confirmation of these results from studies in Ontario (Cook et al., 1974) and in a series of 1,047 women fluoroscoped in two Massachusetts tuberculosis sanitoria (Boice and Monson, 1977).

In the instance of studies of women treated by x-ray for post-partum mastitis, Upton reports an absolute risk of 9.2 cancers per 10^6 per year per rad in women over the age of 30 at the time of treatment and 7.9 cancers per 10^6 per year per rad in those women treated at a younger age. The estimated dose range was 40 to 400 rads. The series of women studied was quite small, 36 cancers in 571 women treated in both age groups.

In women who survived the irradiation from the atomic bombs and were aged 10 or older at the time of exposure a total of 187 cases of breast cancer were reported between 1950 and 1969 (MacGregor et al., 1976). Incidence increased with dose, estimated between 0 and 200 rads and resulted in a calculation of about 2.4 cases per 10^6 per year per rad.

There are several smaller series of cases of breast cancer reported in the literature. These series report cases following irradiation for acne, cases of cancer in the contra-lateral breast following radiation for cancer of the opposite breast, and so forth.

As indicated earlier, doses to breast have been estimated to have been as high as 40 to 45 rads to skin surface in earlier mammography techniques. The doses are much lower with newer techniques of shielding and screening. The breast tissue dose as estimated by Upton et al. would have been about 1.2 rads in earlier techniques and modern techniques would decrease the dose by about a factor of 10. By comparison, the dose to the breast in fluoroscopic examinations of the chest is estimated as 1 to 10 rads per examination.

The Upton group, using information from the studies just cited an animal model experimental results, go on to postulate that "for a single examination, with a dose of 1 rad, the estimate of 3.5 to 7.5 cancers per million person-years per rad corresponds to a range of relative risk of about 0.15 to 0.30 percent per rad for women aged 35 at exposure, progressively less with age for older women (e.g., about 0.06 to 0.12 percent for women aged 65). Continuous exposure at the level of 1 rad per year, starting at age 35, might increase the lifetime risk thereafter by perhaps 4 to 8 percent of the natural risk; i.e., from a natural risk of 7.6 percent to perhaps 7.9 to 8.3 percent."

The postulated model by the group is a modification of the absolute risk model in the 1972 BEIR Committee report. If a hypothetical population of 35-year old women were irradiated once, with a dose of 1 rad to each breast, the model would predict that no radiation-induced cancers would begin to appear until the women reached age 45, 10 years following irradiation, at which time an excess of 3.5 to 7.5 of breast cancer would appear each ensuing year in the population for every million irradiated survivors at risk. If the women were postulated to receive an additional 1-rad dose to each breast every succeeding year, the successive increments of risk would become additive; i.e., the excess would increase from 3.5 to 7.5 cases at the end of the first 10 years to 7 to 15 cases per million after the 11th year, and so forth. If this model were applied to the screenees in the HIP study, with the simplifying assumption that all 30,000 women entered the program at age 35, received 4 successive annual mammographic examinations involving an average dose to the breast of 2 rads per examination, and survived for up to 40 years thereafter without any intercurrent mortality from causes other than cancer of the breast, the maximum cumulative number of radiation-induced breast cancers that would be predicted to result in the population by the time it reached age 75 would be some 25 to 54 cases, an increase of roughly 1 to 2 percent in excess of the approximately 2,300 breast cancers that would be expected to occur in the population through natural causes. If, of course, appropriate allowances were made for the age-distribution of screenees at risk, the estimated numbers of radiation-induced cancers would be far smaller.

In contemplating the potential hazards of mammography, it is noteworthy that the same average risk may look different to the individual than to those making policy for the public at large, because even a small risk to the individual gains significance when applied to millions in the population. So it is here, where the estimated cumulative effects of a single mammogram in a woman aged 35, involving a dose of 1 rad to each breast, would increase the lifetime probability of developing cancer from an average risk of about 7.58 percent to a level of about 7.59 to 7.61 percent, while the corresponding incremental risk in a million women would amount to roughly 110 to 240 excess cases of cancer. If such examinations were to be repeated annually, the average risk to the individual would be estimated to rise from the natural level of 7.58 percent to about 7.90 to 8.25 percent, while the excess cancers induced in a million women would be estimated to approximate 3,100 to 6,700 cases.

Another way of looking at risks associated with mammography has been expressed in a paper by Fabrikant and Hilberg, which is in press (2).

A rough estimate of the radiation hazards from all malignancies associated with the mammographic examinations in the New York Health Insurance Plan study has been determined based on the following assumptions:

1. 20,000 women examined with an average of 3.2 x-ray studies per woman;

2. the breast tissue dose was 2 rads, the lung dose 0.2 rads, the bone marrow dose 0.04 rads, and other tissue dose 0.02 rads;

3. the carcinogenic risk is linear, the women were exposed at exact age 55, the midpoint of the plateau period was 14.5 years with respect to leukemia, and 30 years with respect to all other organs, and years of life expectancy are not taken into account.

The number of expected deaths from cancer, therefore, was: breast 3.5; lung, 0.2; leukemia, 0.05; and other, 0.01; the total is approximately 4 cancer deaths at all sites due to radiation exposure. The data suggest that the cancer deaths appear to be equivalent to approximately one-tenth of the breast cancer deaths avoided in the first 6 years, suggesting a safety margin (benefit/cost ratio) of a factor of 10. The new techniques of dose reduction could improve the benefit-cost ratio by an additional factor of 10; i.e., by a factor of 100. However, mammographic procedures that are not carefully controlled could employ radiation doses much greater than in the controlled Health Insurance Plan study, and the safety margin (benefit/cost factor, deaths avoided/cancer deaths induced) would be correspondingly reduced. Furthermore, mammography studies indicate that the procedure for women under age 50 does not result in a decrease in breast cancer deaths and the risk of radiation-induced cancer is greater, so that mass mammographic x-ray screening of younger age-group women would appear to involve a net hazard.

In a report published in April 1977 concerning the 27 breast cancer detection demonstration projects jointly sponsored by the National Cancer Institute and the American Cancer Society (3) several observations were made:

1. That the women examined in these projects appear to be heavily weighted toward those considered to be at a higher risk of breast cancer. Also these higher-risk women tended to return for the second annual screening more than lower-risk women.

2. The gains through screening detection of breast cancer per woman screened are modest.

3. For the initial or second annual screening series, the highest gain among the groups studied is 0.08 years per screenee. For a given screening, the upper limit of the presumable loss due to radiation-induced breast cancers is perhaps 0.006 years per screenee at ages 35-39 and 0.001 years per screenee at ages 55-59.

4. Except in 35-39 year old women, the estimated detection benefit is many times the presumed radiation loss at initial screening.

5. The "major" risk indicators delineate a small proportion of women who are at substantially higher risk of developing breast cancer and who show more gain from screening than the large majority of women of their age.

In summary of this brief presentation of risk factors to consider in mammography as well as in a consideration of the whole problem of breast cancer, possibly a statement appearing in a publication by the Bureau of Radiological Health in October 1976 presents a clear position which should be considered:

> "Valuable therapeutic and diagnostic x-ray techniques which are of great benefit to patients cannot be abandoned because of the risk of delayed harmful effects; on the other hand, if the same diagnostic information or therapeutic results can be obtained using techniques which reduce radiation exposure to the patient, or if equally effective non-radiologic procedures which do not involve such risks are available, such methods should be used." (4)

REFERENCES

1. DHEW Publication No. (NIH) 77-1400, Final Reports of National Cancer Institute Ad Hoc Working Groups on Mammography Screening for Breast Cancer and A Summary Report of Their Joint Findings and Recommendations, March 1977.

2. Fabrikant, Jacob I. and Albert W. Hilberg. A Cost Benefit Analysis of Mammography Used as a Screening Procedure (in press).

3. Seidman, Herbert. Screening for breast cancer in younger women: Life expectancy gains and losses, Ca-A Cancer Journal for Clinicians, Vol. 27, No. 2, March/April 1977.

4. Barnett, Mark H. The Biological Effects of Ionizing Radiation: An Overview, HEW Publication (FDA) 77-8004, October 1976.

WHAT CAN AND NEEDS TO BE DONE BY STATE/LOCAL RADIATION CONTROL AGENCIES

Alice Dolezal
Section of Radiation Control
Minnesota Department of Health

What can and needs to be done in mammography by State and Local Radiation Control Agencies? In order to know how to proceed with such a question, it is necessary to know where one is now. This was exactly the position in which the Radiation Control program found itself when someone introduced a bill in the State Legislature to establish breast cancer screening centers in Minnesota. Since we have a radiation source registration program in Minnesota, we knew where the mammography machines are located. What we did not know was the exact or even approximate exposure per examination that is given at each location, which film screen combination or xerox procedure is used, and approximately how many women are having mammographs. in other words we really did not know a great deal about the current mammography practice in Minnesota. But with focus in the Legislature on mammography we were jolted into a rather hurried program to determine at least the exact procedure used with each machine and the exposure per exam. While we were still just gathering the data, the Health Department informed the Legislator who introduced the bill that we could not support the bill as it was proposed for many reasons. The Minnesota Medical Society, the Cancer Society, and others were not satisfied with it either. As with so many things this turned into a "hurry up and wait" game.

The time spent in gathering data was by no means lost for us though. In order to obtain the basic information needed we joined the Bureau's BENT program even though it was only in the pilot stage. Through this program we have developed a comprehensive and very advantageous program with users of mammography machines.

Using the guides for exposure per film as proposed by the Bureau of Radiological Health we visited each of the facilities that were either too high or unusually low. We worked with the operators and radiologists at each facility to obtain satisfactory images within the exposure range of the guide.

Although the initial circumstance and need that we experienced may not exist in your State, the very basic information on mammography examinations can and should be obtained. It may be quite a surprise for you to know exactly how much radiation is being administered by some of the mammography machines in your State. As part of the goal all of us share, i.e., elimination of unnecessary radiation, this is a very real situation. In Minnesota the highest exposure was just over 5 R for the craniocaudal view. Adjustments for patient size and type of view have to be made, of course. But in round numbers for a typical exam with two views, a woman received about 21 R. The Bicehouse study showed some much higher. After we worked with the facility, acceptable mammographs were obtained by using 2 R for the craniocaudal view. This resulted in approximately 8 R per exam or 13 R per exam less than before we worked with the facility. This particular facility happens to be a large hospital with a comparatively large number of mammographs taken daily. With the reduction of 13 R per exam, this represents an impressive reduction in radiation exposure in a month. If one were to calculate the exposure reduction across the State, the number would be staggering.

An important point to remember throughout the program is that the purpose is to get a diagnostic quality image at the lowest possible exposure. So while in some facilities, as in the example used before, we were able to reduce the exposure per exam, in others we were concerned because the exposure was so low. We were concerned that the images being obtained were not good diagnostic quality. After working with the facility to get a radiograph or xerograph that was really acceptable to the radiologist, we found the exposure per exam had increased. The exposure was still within the guides, but the radiologist was better satisfied with the radiograph because the diagnostic quality had improved. We have found that in working with the operators and radiologists, good results are achieved that are satisfactory to them. We are also relatively confident that those techniques will be used after we leave the facility. The operators and radiologists have also become quite conscious of the exposure per film. Requests to retest the machines are now received after the service or repairman has made some adjustment. This exemplifies another important "need." The State regulators need to work with facilities to help them become increasingly conscious of reducing radiation exposure. Both radiologists and operators could hardly believe the actual exposure before modification. The mammography program has helped the radiologists and operators become more conscious of exposure for at least this procedure.

As part of the program, it is necessary for the inspectors to keep abreast of the current standards and accepted practices. Agencies such as the Bureau of Radiological Health, National Cancer Institute, and American College of Radiology occasionally publish guidelines. It is also important for State inspectors to know the various kinds of machines, tubes, and image receptors that are being used. Less radiation is required with some equipment and image receptors than with others. The inspector has to know what to expect from the equipment at the facility and advise accordingly. In many instances the inspector is the only source of information on this equipment other than the company representatives. A need exists for training operators of mammography machines on how to achieve the lowest exposure while still obtaining diagnostic quality images. Many of the operators did not receive training on the use of mammography machines before they were certified. Some on-going training is needed to update the current operators. The State Medical Society should also be aware of the program. We can't wait for a formal certification program.

One of the results of the mammography program in Minnesota was that we began to work with other Sections and Divisions of the Health Department in an area that had not been coordinated before. The Sections for Cancer Control, Epidemiology, Chronic Diseases and Public Education from the Department became involved. In addition we have input from the Minnesota Medical Society, the Cancer Society, and the public. Because of the publicity that the topic of mammography has received in the recent past, it is imperative that all concerned agencies be given an opportunity for input in whatever policy the State adopts.

Although the proposed legislation in Minnesota did not pass yet, we have in our State, as many of you probably have, individual facilities that conduct breast cancer screening programs. Because of the volume of patients that subsequently have mammography as a result of this screening, it is important that the Radiation Control Program be aware of the type of equipment and techniques used. The criteria for selection of the women undergoing mammography should be discussed with other sections in your Department and the facility performing the screening.

Although circumstances may necessitate gathering certain types of data, a State or local Radiation Control program may conduct a mammography study for the sole purpose of gathering information on the x-ray units used for mammography. This basic information may then be utilized for various purposes. It may, for example, serve as the basis for a simplified quality assurance program in achieving the best diagnostic image at the lowest exposure. If there are pending legislative actions or other special programs at the State or local level on regulations or guidelines for the use of mammography, the information on the existing types and numbers of units, the type of image receptors, and the range of exposure levels being used would be very important. It is important to utilize information from research centers, NCI, BRH and other groups conducting research. The need for a quality assurance program may become obvious as a result of the information and data gathered on the existing mammography units. This quality assurance program may be developed by the State or local Radiation Control Program, or an existing program, such as BENT, may be adopted. The interaction of the Radiation Control Program with other divisions within the Department and among professional societies regarding breast cancer screening and the methods of detection is an important aspect of a quality assurance program. Through this interaction a Radiation

Program can acquire valuable information, which, in turn, increases the capabilities of the Radiation program and its quality assurance program.

There is an urgency for initiating a program to obtain basic information for radiation control programs needed in determining radiation exposure during mammography. To obtain diagnostic quality images and eliminate unnecessary radiation, a quality assurance program and training of operators will be necessary in many instances. Much research is being conducted currently, and refinement of guidelines will continue. However, State and local radiation control programs must initiate studies to obtain the basic information and to eliminate unnecessary radiation in mammography.

DISCUSSION

MR. PARKER: The Washington Post, Dr. Lester, has characterized the 27 breast detection projects sponsored by the ACS and the NCI, as having the potential of having the largest medical scandal in history. I wonder if you would care to comment on that.

DR. LESTER: That is kind of a global question, you know, to which there is no good answer, particularly since I did not read the article. In all candor, I do not understand and cannot understand, irrespective of what they believe the outcome of the program has been to date, or will be in the future, how well-meaning people can make such a statement. To me, irrespective of the final conclusion of the program, this was, at its time, a reasonable effort be well-intentioned, knowledgeable scientists and physicians to further the practice of medicine as they perceive it to be done appropriately.

Furthermore, let me say, in fact, my own analysis of the preliminary results of that program shows a rather striking benefit. I believe that if the statistical problems, which are very severe, can be resolved, that it will be of benefit to the furtherance of medical science as well as to the now approximately 1,000 women whose breast cancers were discovered during the course of this work so far. I have a great deal of respect for the Washington Post, but I think whoever wrote that headline had a bad headline.

MR. FISHER: Are the centers collecting information on mammography installations throughout the State?

DR. MALONE: No, the only information that the Cancer Institute is collecting any information on is in the BCDDP program in the 27 centers. Any information that is being collected on mammography units in the States would not be collected by the State people.

Dr. ALCORN: I am from Chicago; I am a radiologist. I have a question I would like to address to Dr. Hilberg. In the NCRP bulletin 43, they state specifically that they did not feel that, based on any experimental evidence, numerical risk/benefit ratios should be calculated. In a publication by a National Academy of Science on the biological effects of low-level ionizing radiation--I do not mean the Bureau report, the other one--that there really was not the proper evidence available to make risk/benefits. And all of a sudden, in spite of this (and we note that the names on the committees are pretty much the same on both, including Dr. Upton, and I have talked to him about this), we are coming out with these risk/benefit ratios. I would like to know what has prompted this in the face of these publications by these well-known and recognized scientific committees of very important persons in the field.

DR. HILBERG: Concerning the NCRP Number 43, I think that the NCRP is perfectly entitled to its approach which, as an aside, I might say, I happen to agree with. However, the BEIR Committee in its 1972 report very clearly states that it seems to be, in the lack of evidence, either for or against a linear hypothesis versus a threshold hypothesis, it is a most prudent thing in making calculations, and this I want to make very clear, that a linear hypothesis be used. This does not (and the BEIR Report makes it imminently clear in several places) that these are real, these are genuine; they are extrapolations using a linear hypothesis.

You referred to a second report that I am not quite familiar with, unless you're referring to the nuclear BEIR report in costs, which is in press. Then you also asked where these other risk estimations are coming from by Upton and group. This was a study done by Dr. Upton for the National Cancer Institute, not for us. I was quoting directly from that study to make sure that I had his risk estimates correct. This has neither been reviewed nor approved in any sense by the advisory committee on the biological effects of ionizing radiation.

CT SCANNING'S PLACE IN DIAGNOSTIC RADIOLOGY

Ronald G. Evens, M.D.
The Edward Mallinckrodt Institute of Radiology
Washington University School of Medicine

INTRODUCTION

Until recently, diagnostic radiologists have been limited to interpreting two-dimensional images which superimposed many important organs. Radiologists, and their colleagues, were ingenious in developing new equipment, contrast agents, and improved techniques to further their diagnostic skills; but the fundamental difficulty in evaluating three-dimensional structures with two-dimensional images remained a significant factor. Radiographic tomography (moving the tube and film in a variety of patterns in order to "blur" structures outside of a specific plane of interest) was useful to reduce the problem of overlapping structures in certain areas of the body, but the "blurring" added to the problem of density resolution.

The specialty of radiology was changed by the dramatic introduction of computed tomography (CT) (1). His adaptation of computer technology and techniques of image reconstruction to modern radiologic equipment permits the generation of images of the human body as a series of reconstructed cross-sectional pictures. The original equipment was limited to analyzing the cranial vault--primarily because of the several minutes required for scanning and the need of a water bag around the area to be studied. In a few short years, many improvements have been introduced and equipment is commercially available that allows scanning times of a few seconds, does not require a water bag, and can accurately measure the attenuation coefficients of biologic materials with the precision of 0.5 percent and a spatial resolution of approximately 3 to 5 mm.

Many choices of computed tomography equipment are now possible. In all cases, the equipment consists of four parts: (1) a scanning gantry, (2) patient couch, (3) computer, and (4) a viewing unit. The scanning gantry consists of an x-ray source which produces a highly collimated x-ray beam that passes through the patient to an array of detectors mounted diametrically opposite the x-ray tube. The data accumulated during each scan are processed by the computer, and the reconstructed image is displayed on a television monitor for viewing and subsequent photographic recording. The reconstructed image can be manipulated on the display console to permit selective display of any range of absorption values from the wide spectrum obtained during a scan.

PRESENT STATUS OF CT

CT of the Head

Many medical centers have used CT in neuroradiology for more than 4 years. As of January 1976, approximately 150 units were in operation throughout the world and thousands of examinations have been reported (2-6). I now estimate more than 750 installations are now in operation.

The cranium can usually be evaluated with eight slices (four scans) and the appearance of normal tissue is well documented. Approximately 60 percent of patients are studied before and after contrast (7). The presence of bony lesions, deformity or volume change of the fluid containing spaces within the brain, and variations in the tissue density of the brain allow a wide variety of diagnostic observations. The CT findings in primary and secondary brain tumors, cerebral vascular accidents or "strokes," trauma to the brain and skull, and degenerative neurologic processes have been reported and CT is rapidly becoming the primary diagnostic imaging procedure for most neurologic diseases. We have recently summarized the data that demonstrates a significant improvement in diagnostic accuracy with CT when compared to other diagnostic procedures and especially the radionuclide brain scan (8).

The rapid clinical acceptance of head CT is not only related to its high accuracy, but also to its significant effect on the management of many patients. Neurologic therapy is determined and evaluated by CT findings. For example, certain categories of patients with a clinical "stroke" are treated with anticoagulation. This treatment has a definite morbidity in patients with a hemorrhagic stroke. CT accurately detects intracerebral hemorrhage, even when the spinal fluid examination shows no blood and the patient's treatment is appropriately directed. Other examples include patients with head injuries, parasellar masses, and following radiation therapy (9-11).

Head CT has reduced the need for other diagnostic tests that are expensive, difficult or dangerous. Cerebral air studies have diminished by approximately 60 percent, cerebral angiographic procedures by approximatey 30 percent, and radionuclide brain scans by approximately 30 percent at the Mallinckrodt Institute. Similar patterns of utilization have been reported from other institutions and cranial CT is a cost-beneficial procedure (8,12).

Body CT

By 1975, CT equipment had been modified by at least two manufacturers so that an overlying water bag was not required and all portions of the body could be placed between the x-ray beam and the crystal detectors. Scanning time was still 2 minutes or more and respiratory motion was a significant problem. In this same year, Housfield announced a second generation CT unit that was capable of completing the scan in less than 20 seconds and produced dramatically clear images of the abdomen and thorax (13,14). Several institutions have now studied 1,000 patients or more and the clinical efficacy of body CT is being defined and reported (15).

CT easily delineates many normal structures, including major blood vessels. The normal spleen, liver, and gallbladder are of homogeneous density. The pancreas is seen in nearly every patient and the kidneys and other retroperitoneal structures are outlined by surrounding fat density. The bladder and other pelvic organs are delineated and sections through bony structures include a detailed trabecular pattern.

We have now studied more than 2,000 patients and find body CT useful in diseases of the retroperitoneum, liver, pelvis, and to a lesser extent in the thorax. Diagnostic studies of the retroperitoneum are particularly useful, a region of the body that is very difficult to evaluate by previously available methods (16).

CT can correctly diagnose 80 to 90 percent of patients with cancer of the pancreas. Unfortunately, the attenuation coefficient of pancreatic carcinoma is the same as the normal pancreas but anatomical changes with masses greater than 2 cm can be detected. Carcinoma can usually be differentiated from pseudocysts of the pancreas because the cysts have the attenuation density of water and are well-circumscribed. Renal cysts, renal carcinoma, and inflammatory masses can be distinguished by their appearance before and after contrast injection (17). CT is especially useful when ultrasound findings are nonspecific or where ultrasound is technically difficult. Retroperitoneal tumors, abscesses, and lymphoma are identified and quantitated.

The liver is another organ easily studied by body CT. We believe that body CT is the most accurate diagnostic test to differentiate the cause of jaundice and identify dilated bile ducts. Space occupying lesions of the liver are identified by changes in liver morphology and density. The sensitivity of CT is similar (and perhaps higher) to the radionuclide liver scan, however, CT's ability to quantitate tissue density allows a more specific diagnosis (14,18,19). Enlargement of the gallbladder can be detected and some stones have been observed that are not visible by standard radiography.

Tumors of the pelvic organs are detected and extension of tumors from the uterus, bladder, or prostate to the lateral pelvic walls can be demonstrated.

Body CT is useful in certain lesions of the thorax but the chest radiograph is a very sensitive detector of disease and CT is not required with most patients. Nevertheless, mediastinal masses, small pulmonary lesions, and solitary pulmonary nodules have been studied with useful results.

It is obvious that body CT is an important diagnostic technique in a variety of pathologic lesions. It has not yet demonstrated its use as a screening test.

Economics and Dosimetry of CT

CT is revolutionary, but as in other revolutions, it is costly (7). Head CT units in the United States have an annual technical cost of $325,000 to $371,000 per installation. Approximately 50 patients per week can be carefully studied and the average technical cost per patient is $130. Body CT equipment is more costly and fewer patients are studied per day--therefore the technical cost per patient is higher. I am now in the process of analyzing body CT costs and I can estimate the cost per patient will be approximately $200. This relatively high cost per patient creates concern in individuals responsible for health care budgets. Fortunately, CT reduces other diagnostic tests and some of the costs are not additive but replace current expenditures (12).

Nevertheless, the relatively large cost associated with CT has focused great public attention and political interest on its development. This attention and interest will require careful evaluation of CT's medical benefits and their cost. Cost-benefit and cost-efficacy studies require scientific data that is available from head CT studies and will soon be available with body CT (8,20). Improved CT efficiency is an important future goal in order to make this new diagnostic modality available to all patients who can benefit from its use. The cost per patient will be less if more patients can be studied per day (7).

Regarding radiation dosimetry, many participants in this conference have considerably more expertise than I. Dosimetry at our installation indicates that the rad absorbed dose for a body CT scan (10 to 14 multiple views) is approximately 8 rads. Calculations of integral dose indicate a value of approximately 20,000 gram rads. Thus, the radiation dose required for CT is similar (or less) than many diagnostic radiologic procedures and it is the first time in my experience that a major improvement in diagnostic radiology has occurred without an increase in radiation dose required.

My role in this conference is to define the current position of computed tomography as a diagnostic technique. I want to close by indicating my view that the future of computed tomography is even more exciting. Technical improvements in equipment will reduce scanning time to less than 5 seconds and image reconstruction time to a few seconds. This will allow improved images throughout the body (and perhaps allow clinical scanning of the heart) and increase our ability to study more patients per day (21).

CT diagnosis often requires the use of iodinated radiologic contrast agents, particularly in the head. Pharmaceutical research should take advantage of the sensitivity of CT and identify specific contrast agents for the liver and other organs (22). Finally, further clinical experience will undoubtedly improve our ability to use the fantastic amount of information in these scans.

REFERENCES

1. Hounsfield, G.N. Computerized transverse axial scanning (tomography). I. Description of system. Brit J Radiol 46:1016-1022 (December 1973).

2. Paxton, R., and J. Ambrose. The EMI scanner: A brief review of the first 650 patients. Brit J Radiol 47:530-565 (September 1974).

3. New, P.F.J., W.F. Scott, J.A. Schnur, K.R. Davis, and J.M. Taveras. Computerized axial tomography with the EMI scanner. Radiology 110:109-123 (January 1974).

4. Alderson, P.O., M. Mikhael, R.E. Coleman, and M. Gado. Optimal utilization of computerized cranial tomography and radionuclide brain imaging. Neurology 26:803-807 (September 1976).

5. Baker, H.L.,Jr., O.W. Houser, J.K. Campbell, D.F. Reese, and C.B. Holman. Computerized tomography of the head. JAMA 233:1304-1308 (September 1975).

6. Evens, R.G. New frontier for radiology - computed tomography (Fortieth Annual Preston M. Hickey Memorial Lecture). Am J Roentgenol 126:1117-1129 (June 1976).

7. Evens, R.G., and R.G. Jost. Economic analysis of computed tomography. Am J Roentgenol 127:191-198 (July 1976).

8. Evens, R.G., and R.G. Jost. The clinical efficacy and cost analysis of cranial computed tomography and the radionuclide brain scan. Semin Nucl Med 7:129-136 (April 1977).

9. Ambrose J., M.R. Gooding, and D. Uttley. EMI scan in the management of head injuries. Lancet 1:847-848 (April 1976).

10. Naidich T.P., R.S. Pinto, M.J. Kushner, J.P. Lin, I.I. Kricheff, N.E. Leeds, and N.E. Chase. Evaluation of sellar and parasellar massed by computed tomography. Radiology 120:91-99 (July 1976).

11. Norman, D., D.R. Enzmann, V.A. Levin, C.B. Wilson, and T.H. Newton. Computed tomography in the evaluation of malignant glioma before and after therapy. Radiology 121:85-88 (October 1976).

12. Evens, R.G., N. Rujanavech, and M. Mikhael. Utilization, reliability, and cost effectiveness of cranial computed tomography in evaluating pseudotumor cerebri. Am J Roentgenol 129:263-265 (August 1977).

13. Sagel, S.S., R.J. Stanley, and R.G. Evens. Early clinical experience with motionless whole body computer tomography. Radiology 119:321-330 (May 1976)

14. Sheedy, P.F., D.H. Stephens, R.R. Hattery, J.R. Muhm, and G.W. Hartman. Computed tomography of the body: Initial clinical trial with the EMI prototype. Am J Roentgenol 127:23-51 (July 1976).

15. Evens R.G., R.J. Alfidi, J.R. Haaga, G.W. Hartman, R.R. Hattery, E. Kazam, M. Korobkin, A.R. Margulis, T.F. Meaney, S.S. Sagel, P.F. Sheedy II, R.J. Stanley, D.H. Stephens and J.P. Whalen. Body computed tomography: A clinically important and efficacious radiologic procedure. Radiology 123:239-240 (April 1977).

16. Haaga, J.R., R.J. Alfidi, T.R. Havrilla, A.M. Cooperman, F.E. Seidelmann, N.E. Reich, A.J. Weinstein, and T.F. Meaney. CT detection and aspiration of abdominal albscesses. Am J Roentgenol 128:465-474 (March 1977).

17. Stanley, R.J., S.S. Sagel, R.G. Levitt. Computed tomography of the body: Early trends in application and accuracy of the method. Am J Roentgenol 127:53-67 (July 1976).

18. Stanley, R.J., and S.S. Sagel. Computed tomography of the liver and biliary tract, in Radiology of the Gallbladder and Biliary Tract (eds. Berk and Clemett), Philadelphia, W.B. Saunders Company, pp. 352-375 (1977).

19. Alfidi, R.J., J.R. Haaga, T.R. Havrilla, R.G. Pepe, and S.A. Cook. Computed tomography of the liver. Am J Roentgenol 127:69-74 (July 1976).

20. Levitt, R.G., R.G. Jost, J. Trachtman, S.S. Sagel, and R.J. Stanley. A computer-assisted method to determine the diagnostic efficacy of computed tomography of the body. Radiology 123:97-101 (April 1977).

21. Ter-Pogossian, M.M., E.S. Weiss, R.E. Coleman, and B.E. Sobel. Computed tomography of the heart. Am J Roentgenol 127:79-90 (July 1976).

22. Alfidi, R.J. and M. Laval-Jeantet. A promising contrast agent for computed tomography of the liver and spleen. Radiology 121:491 (November 1976).

HOW WILL CT SCANNING AFFECT PATIENT TREATMENT AND CARE?

H. David Banta, M.D., M.P.H.
Office of Technology Assessment
Congress of the United States

I have been asked to address the general question of usefulness of CT scanning. Not being a radiologist, I approach this primarily as somebody who looks critically at the medical and radiological literature. Before I address CT scanning, let me just say a few words about the Office of Technology Assessment for those of you who are unfamiliar with it. The problems of technology and its applications have been of increasing concern to the Congress and to policy makers in general. This led to the establishment of the Office of Technology Assessment in Congress in 1973 to do studies related to technology for the Congress, and the establishment of a health program in that office in 1975.

We had a general request to look at the costs and effectiveness of medical technology in 1975. In April 1976, a specific request came from the Senate finance committee, which has jurisdiction over Medicare and Medicaid, to examine the CT scanner. We prepared what we called a memo that we presented to the committee in June of 1976. We are presently completing the study.

I think it is important for us to recognize that CT scanning is not the problem that should be addressed. The problem that should be addressed is how we deal with medical technology. CT scanning, as Dr. Evens has eloquently pointed out, is a major technological breakthrough. Although it has not been completely studied, and I do not think its place in diagnostic radiology or medical practice is completely demonstrated, it has been quite well studied for a diagnostic technology. What I am concerned about is how we as a nation deal with new and existing technology. I think that many of the things that I am going to say about the efficacy of CT scanning could be applied to diagnostic technologies in general, and many could be applied to therapeutic and preventive technologies as well.

Why are we concerned about CT scanning? The first CT scanner was introduced in 1973 at the Mayo Clinic. It has been a very rapid diffusion, probably an unparalleled diffusion of a medical technology (Fig. 1). By May 1977, we could document 400 operational scanners, but because of the lag time in reporting and so forth I think we can pretty well say that there are 550 operational scanners, since about 20 a month are going operational. And there is no sign that this is going to slow down.

This is what has led to the concern among policy makers and has led people to ask what is the relationship between this rapid diffusion and the efficacy of the technology. One of the main points I would like to make is that although the CT scanner is now proving to be a quite efficacious device in terms of diagnostic accuracy, and there is some information to indicate that it will be quite efficacious in terms of impact on therapy and perhaps even on patient outcome, this diffusion really preceded the demonstration of usefulness. And that, I think, is generally the case in the medical care system.

We would define efficacy as potential benefit from a medical technology. That benefit generally would be health benefit, and in dealing with a therapeutic technology, it would definitely be the contribution of that therapeutic technology to the health of the patient. However, that becomes very complicated in dealing with the diagnostic technology. A diagnostic technology does not impact directly on the health of the patient. The impact on the health of the patient then depends not only on making the diagnosis, but on having an efficacious therapy available to treat the patient afterward. It is difficult to talk about efficacy of a diagnostic technology and not become immediately embroiled in controversy. Nonetheless, most physicians and others would agree that the ultimate goal of both the medical care system and any medical technology is to affect the health of the patient. When I say health, I would certainly define that in broad terms to include reassurance of the patient who is worried, quality of life considerations, and so forth.

Looking at the efficacy of CT scanning in general, much more is known about the head scanner than the body scanner. We have found it very useful to look at efficacy in terms of a formulation suggested by Fineberg, at the Harvard School of Public Health and the Department of Radiology at the Massachusetts General Hospital. Efficacy of a diagnostic technology is seen as having five levels. The first level is technical capability. Does the device produce information that is reliable? That is, the information has a basic validity to it. Second, is the information diagnostically accurate? Does it lead one to a diagnosis that is true? Third, the diagnostic impact or impact on other diagnostic procedures; does the diagnostic technology replace other diagnostic procedures in use? And in diagnostic procedures we would include exploratory surgery. Fourth, does the diagnosis achieved have an impact on the therapy for the patient? And, five, is there an impact on the patient's outcome or the health of the patient?

In terms of technical capability, CT scanning has been quite well studied and there is really no question that CT scanning produces reliable images with the correct dimensions and so forth. At the second level, diagnostic accuracy, there has not been what one could call a well controlled, well designed study of the diagnostic accuracy of CT scanning. However, there has been over the last 3 or 4 years an accumulation of literature that reports quite consistent results with diagnostic accuracy in clinical use, especially for head scanning. Generally, the diagnostic accuracy is about 90 percent depending on the diagnosis. For brain tumors, it is higher: 95 percent or above. For strokes, less, depending on the time of the stroke and so forth. But in general this accumulation of information indicates that CT scanners are quite accurate in terms of diagnosis. The body scanner has not been nearly so well documented. There are probably 10 articles dealing with different organs, mostly in the abdomen, and these show around 90 percent accuracy.

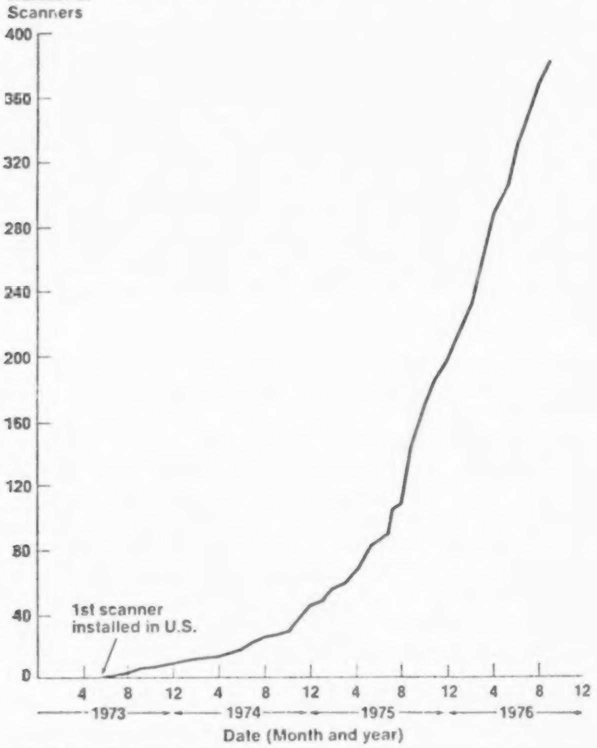
The third level is diagnostic impact. For the head, some of the procedures that are quite often used in neurodiagnosis include arteriography or angiography, pneumoencephalography, radionuclide brain scanning, CT, ultrasound, and others. I have already said the diagnostic accuracy of CT scanning is high, 80 to 90 percent, or probably actually a little higher. Arteriography and pneumoencephalography are not exactly comparable, but when diagnoses are compared, they are approximately the same, 90 percent or above (Table 1). Radionuclide scanning is inferior to CT in most diagnoses.

If we look at the number of procedures, approximately a million CT scans are being done (Table 1). Angiography we estimated somewhere around 200,000. Pneumoencephalography is not a commonly done procedure, and that is important to realize, because quite often people talk about the huge impact on pneumoencephalography. And indeed it is large in percentage terms. But this is a procedure which was not commonly done and was already on the way out. Radionuclide brain scanning: There are approximately two million of these done a year in the United States. In terms of safety, CT scanning is a relatively safe procedure with some radiation dose. The main consideration is some reaction to contrast. Arteriography and pneumoencephalography are riskier. And, so, many would feel that just replacing these riskier procedures with CT would be worthwhile in itself. Radionuclide scanning is similar to CT scanning in safety.

Usable for in/out patients; CT scanning, yes; pneumoencephalography and radionuclide scanning, no (Table 1). And, again, this has been used quite often to justify CT scanning on the basis of cost effectiveness. Unfortunately, overall, as well as we find out, more than half of the CT scans are done on hospitalized patients so that the potential of CT scanning to reduce costs by keeping the patient out of the hospital is not being realized. CT scanning could perhaps pay for itself if used on outpatients.

Finally, the effect of CT scanning on utilization: modest decreases in arteriography, large percentage increases in pneumoencephalography, modest decreases in radionuclide brain

CT Scanners in the United States by Date of Installation



SOURCE: Office of Technology Assessment

Figure 1

Table 1. Comparison of CT head scanning with other neurodiagnostic procedures

Procedure	Diagnostic Accuracy[11]	Approximate Annual Numbers of Procedures in United States, 1976	Safety Compared to CT Scanning	Usable on Outpatients	Estimated Effect of CT Scanning on Utilization
CT scanning	High-generally 80-90%	855,400-987,000	-	Yes	-
Arteriography	Similar to CT	100,000-350,000	Riskier	No	-20% to 0
Pneumoencephalography	Similar to CT	25,000- 50,000	Riskier	No	-40 to 75%
Radionuclide scanning	Inferior to CT	2,000,000	Similar	Yes	-90 to 15%
Skull x-ray	Used for purposes different from CT; inferior when compared	4,000,000	Similar	Yes	Little or no effect

Estimates of Office of Technology Assessment scanning (Table 1). In terms of radionuclide brain scanning, CT scanning seems to be considerably superior. Cleveland Clinic has reduced its radionuclide brain scanning to 15 percent of the pre-CT level in 1976, according to Dr. Ralph Alfidi. With the charge that Cleveland Clinic uses for CT scanning, that almost pays for the cost of CT scanning.

Such a result could be realized for the entire country.

The other area of diagnostic impact is the area of exploratory surgery. CT scanning has a tremendous potential for preventing exploratory surgery. There is not a great deal of data on this. But there was a study from London showing that before the introduction of CT, 33 percent of patients with head trauma ended up having exploratory neurosurgery. After the introduction of CT scanning, only 2 percent had exploratory brain surgery. And there is some data from Massachusetts General Hospital that shows a similar result, both for head and for body scanning. I will come back to that in just a moment. On diagnostic impact, there is little known about body scanning, according to the literature.

The fourth level is the impact on the planning or delivery of therapy. There is only one study of impact of head scanning. Dr. Fineberg at Harvard, in cooperation with the Department of Radiology, has done a study of head scanning that has shown that therapy plans were changed in about 15 percent of patients who were scanned. The Harvard group has now replicated that study for body scanning and the findings were similar for areas of the body that are known to have high payoffs. The investigators selected eight areas based on clinical experience with body scanning around the country. Dr. Evens has discussed, I think, all of these; the kidney, the liver, the pancreas, and so forth. And in those eight areas, 15 percent of the patients had their therapy changed. It is interesting, though, that in both of these studies, many of the changes were to prevent surgery. A relatively small number of patients had positive therapy changes as a result of CT scanning. However, to have patients not be subjected to unnecessary surgery is quite a good outcome.

And, finally, at the level of patient outcome, or improvement of health, very little is known about CT scanning. In one study from London of head scanning in head trauma, there was no change in mortality after introduction of CT scanning. That is really the only information that we have. We could predict that just preventing unnecessary surgery is going to lead to an improved patient outcome, at least in the short run. Other than that, little is known.

As for use of contrast, very little is published that can be analyzed statistically. For the head, it is known that a small percentage of lesions are not seen on a plain scan that are seen after the injection of contrasts, perhaps 2 to 4 percent. In addition to that, contrast does show up the lesions better for patients who are going to surgery. For example, it seems to be justifiable to use contrast to show up the extent of the lesion, but it is not at all clear how often contrast should be used in ideal practice.

A related point, having to do with efficacy, is the question of indications for use, because patients generally do not present saying, "I have a pancreatic cancer." They present saying, "I have a pain in my abdomen," or, "I have a problem with my appetite," and so forth. As all physicians know, these complaints can be quite vague at times. So, it is really a critical question, when presented with a patient, what patient is likely to have a medical problem that can be helped. The amount of information that is available on this point is small. There are value judgments imbedded in this whole question. For example, is a clinical stroke an indication for use? It has not been a well studied area, but there is one study from a hospital here in Seattle that shows the use of CT scanning with stroke made no difference in the therapeutic plans or the outcome for those patients. Let us assume for the moment that this finding is true: should patients with strokes be scanned to see the extent of the stroke and to gain prognostic information? That is a value-laden question that the medical profession and the broader society have to deal with. Aside from that, we know, for example, that many patients are being scanned with headaches who have no abnormal findings on physical examination. There are now two good series that show that the payoff is essentially nil in this clinical situation. Another kind of indication is trauma. Patients who have normal neurologicals have essentially 100 percent normal CT scans, or at least CT scans that have findings that are not clinically significant. But in general, this question just has not been well examined at all.

Risks involve the risk of radiation itself, the risks of contrast and the risk of anasthesia when it is used. Dr. Evens discussed this, and in the interests of time, I will not say more on this subject.

Let me just mention the question of cost for a moment (Table 2). We have survey survey data on revenue on CT scanners in 1976. Knowing how many there are, knowing how much the charges are, we can say that the revenue from a machine, if it does 3,000 scans a year, which is usual, is around $550,000. The cost is about $350,000 for operating the machine, so that there is also some profit left over to the radiology department, or the institution, or the radiologist. Obviously, the price of CT scanning could be reduced. Even the lowest cost would be fairly high, however.

We did some calculations of aggregate costs of CT scanning, including the scanning itself and the savings from replaced diagnostic procedures. We find a net expenditure for 1976 of 180 to 390 million dollars (Table 3). Of course, that is a cost that is going to increase unless there are substantial effects to see that CT recognizes its potential in terms of replacing other diagnostic procedures, in terms of keeping patients out of the hospital, and in terms of preventing unnecessary surgery.

I just want to say one word about health planning. In the absence of good efficacy information, it is very difficult for the planners to say how many CT scanners there should be. Despite the fact that the head scanner has been fairly well documented by this point, the information is not such that one can say how many CT scanners there should be.

In summary, CT scanning is an exciting technical advance with some risk that is very costly. I would agree with Levitt, et al., from Dr. Evens' department, who said in the Journal of Radiology this April, "Whatever the diagnostic efficacy of CT is, it should not become a part of the radiological armamentarium unless it significantly affects patient management."

(Documentation for this presentation may be found in "Policy Implications of the Computed Tomography Scanner" published by the Government Printing Office, October 1977.)

Table 2. Estimated average annual profits from a CT head scanner, 1976

Dollars	Low	High
Average charge per examination	240	260
Average revenue[iii]		
.30 x average cost		
+.70 x average cost	222	207
(Number of examinations	2,600	3,000)
Total gross revenue	577,200	621,000
Less bad debts[vi]	57,200	62,100
Total net revenue	519,480	558,900
Average total cost per examination	180	83
(Number of examinations	2,600	3,000)
Total costs	468,000	269,750
Average profit	51,480	289,150
(Percent of original purchase price[ix]	12	65)

Source: Office of Technology Assessment

Table 3. Estimated net expenditures for CT scanning, 1976

Thousands of Dollars

	Low	High
Gross Expenditures, CT Examinations	294,999	428,384
Reduced Expenditures	113,318	38,336
Radionuclide brain scans	37,499	17,375
Pneumoencephalograms	53,944	8,790
Arteriograms	21,875	12,171
Net Expenditures, CT Examinations	181,681	390,048

Source: Office of Technology Assessment

PLANNING ASPECTS OF CT SCANNING

Patricia A. Gempel
Senior Professional Staff Scientist
Arthur D. Little, Inc.

INTRODUCTION

Since its introduction to the medical community in 1972, computed tomography (CT) has caused a lot of commotion. In the clinical community, a new technique has become available and there have been many changes in medical practice. In the commercial/industrial world, a new technological and financial race has been going on, and fame and fortunes have been gained and lost. At the Food and Drug Administration's Bureau of Radiological Health, a new set of x-ray exposure problems has been identified, that is more complicated than any encountered previously. For the health planner the introduction of CT occurred at the same time as the implementation of Public Law 93-641, The National Health Planning and Resources Development Act of 1974, which signaled a refined regulatory environment for the health care system in the United States.

This presentation emphasizes health planning activities related to computed tomography. Issues are identified, and some answers provided insofar as is possible. The presentation is divided into three sections:

I. An introduction into health planning as its exists today: where it derives its authority, what the scope of health planning is, and how far along we are in implementation of planning;

II. A summary of some technical changes that have occurred in computed tomography systems and how many scanners are actually operational or sold; and

III. An analysis of health planning as it relates to CT: a definition of the planning issues, planners' priorities, and a summary of guidelines for CT.

HEALTH PLANNING

Health planning is not new in the United States, but it is gaining more power through legislation and funding. In 1974, the National Health Planning and Resources Development Act was passed to correct the deficiencies of earlier legislation. Originally to be implemented by December of 1976, the Act was scheduled for revision and amendment in June of 1977. That revision process has been postponed for another year to allow time for further consideration of changes.

Although the objectives of Public Law 93-641 are many and complex, they can be summarized in two sweeping generalizations:

(1) Improve health care delivery, particularly to the presently underserved portion of the population, and

(2) Reduce or minimize costs.

The implementation of the law is through the development of a multilevel health planning network (see Table 1). This network, which was to be in place by December of 1976, is more than 95 percent complete today.

Table 1. Multilevel health planning network

National - Health Resources Administration
- National Technical Information Center

Regional - Regional Technical Information Centers (10)

State - State Planning Agencies (56)

Local - Health Systems Agencies (202)
(Principal Planning Unit)

At the National Level is the Health Resources Administration, including six major groups active in health care planning:

The Bureau of Health Planning and Resources Development,
The National Center for Health Statistics,
The National Center for Health Services Research,
The Bureau of Health Manpower,
The Division of Long-Term Care, and
The Office of Health Resources Opportunity.

In addition, **The National Technical Information and Research Center** was established through a 5-year grant to the University of Missouri. The charge of this center is to provide general assistance to the health care community in dealing with changing health care technology. There are 10 **regional technical information centers** whose purpose is to assist local agencies and encourage regional cooperation and interaction. They are to train, consult with, and support generally the local planners. Eventually, they will assist in developing methodologies for planning and approaches for improving the health care system. At the State level, **State Planning Agencies** oversee and guide local agencies and consider appeals from health care providers as needed.

Finally, the principal planning unit for the entire network is the **Health Systems Agency**, of which there are 202 in the United States.

The responsibility of HSA's is basically to improve the **quality** of and **access** to health care in their region while at the same time reducing costs. A broader charge of the HSA's with perhaps farther reaching implications is to devise methods for and encourage the delivery of better medical care for their region. Most HSA's have just begun to tackle this assignment, but they are already making progress. Their first task is to develop a regional health care plan, describing existing health care services and making suggestions for improvements.

Part of this activity includes a review of proposed institutional capital expenditures for equipment and services in amounts of more than $150,000. ($150,000 is the minimum set by the National Law. Individual States may lower this minimum by passing State Certificate-of-Need legislation.) Prior to enactment of Public Law 93-641, many States had no controls on capital expenditures including those for bed additions and new service additions. Today, all States must participate in project review for capital expenditures of more than $150,000. In some States that ceiling has been lowered to $100,000 (49 percent of all States); $50,000 (12 percent of States); and $24,000 (5 percent of States). The remaining States have no certificate-of-need legislation (12 percent) or have a limit equal to or higher than the $150,000 Federal level. Those States without CON requirements and those with requirements higher than the national law (which must be revised downward) comprise 17 percent of all States. The sum of all States using $150,000 as the level of capital expenditure requiring CON is thus 34 percent using $100,000 as the minimum and 17 percent having a lower limit.

Project review, or issuing of certificates-of-need, is not limited to diagnostic medical technologies such as new CT units. It includes preventative, therapeutic, and administrative technology as well. Practically speaking, CT is only a small percentage of the capital expense budgets of hospitals (about 2 percent). However, because of its newness and the fact that many hospitals are adding this new service, CT has represented a high percentage of all applications considered under project review, as illustrated in Table 2.

Table 2. HSA project review experience

Project	Total Applications (percent)
CT Scanning	27
Kidney Dialysis	24
Radiation Therapy Equipment	18
EMS Transportation	8
Neonatal ICU	8
Cardiac Surgery and Cath.	7
Burn Units	3
Other	5
Total	100

Health care planning is expensive. In fact, the cost of keeping health costs (health care planning) down is a matter of concern. In 1976, the cost was $0.26 per capita; in 1977, it will probably be $0.40, and by 1978, $0.50. The 1980 projection is $1.00 per capita. If this trend continues, the annual cost of health care planning will approach $200,000,000 by 1980.

OPERATION AND EVOLUTION OF TECHNOLOGY

CT and conventional radiology are similar in that anatomical detail within the body is revealed pictorially by virtue of the detection of differing x-ray absorption values in different types of tissues and structures. In a conventional system, the object of interest is placed between a source of x rays--usually an electrically powered x-ray generator--and a detector, which is generally a sheet of photographic film held closely between two radioluminescent phosphor screens. The diverging cone of x radiation is partially blocked and partially transmitted by the portion of the body under examination, and that which is transmitted is detected by the phosphor-film combination. Denser components such as bone transmit relatively little radiation; lighter ones such as fat, water, and air transmit relatively more. Frequently, two or more views will be taken, typically at 90° to each other, to help in identifying features that may be superimposed and, therefore, obscured in a single view.

In CT, the film and phosphor screen detection system is replaced by a battery of miniature electronic x-ray detector cells. Each of these detectors is only a few millimeters in diameter, and each of them measures the intensity of the x-ray flux it sees, transmitting this information to a computer, which stores and processes all the data, eventually converting it into images. Because of this capability to detect an x-ray flux electronically, and to convert it into digital data, CT allows the full power of the modern computer to be used, thus enabling a new dimension to be revealed in radiology. The system starts by making projections through the body, not just along one or two axes, but in more than a hundred different angular positions, as a yoke carrying the x-ray source and its opposing detectors rotates around the patient's body.

In order to preserve a reasonable amount of simplicity in the early models, all commercial CT units produced so far have been true tomographic devices, in that they examine only one narrow slice or section of the body at a time, a feature which may eventually be abandoned as later designs acquire greater sophistication. A narrowly confined fan-shaped beam of x rays only a few millimeters wide is directed through the patient's body toward a linear array of detectors. As the source/detector yoke rotates, each detector measures the varying intensity of x-ray flux that reaches it, and the computer records the value for each location of each of the intersecting beams. When all angles through one section have been probed in this way, the computer proceeds to solve a complicated set of simultaneous equations, from which it calculates the x-ray absorption value for each of several thousand or tens of thousands of locations in that slice. A mosaic of different shades of light and dark is thus constructed, which can be displayed on a cathode-ray oscilloscope screen or a TV monitor.

A permanent record can be obtained either by photographing the video image or by some form of direct hard-copy printing.

At the discretion of the radiologist, any number of successive section scans can be made, parallel to the first, so that a full three-dimensional examination can be made if desired. Ordinarily, such successive sectional images are displayed as individual photographic prints for the radiologist to study. Some of the more advanced systems permit reconstruction of off-axis images in any plane of view, provided, however, that enough serial sections are made initially to furnish the data necessary for such a reconstruction.

A major limitation of early CT units, and one which fortunately continues to yield to the determined efforts of clever physicists and engineers, is that of the long time required for the CT examination. Initially, single section scans required as long as 5-1/2 minutes to complete. Scan times on some recently introduced machines have been reduced to less than 10 seconds, as a result of a number of refinements in CT technology between 1972 and 1976. These changes, as summarized in Table 3, have been in the shape of the x-ray beam and the arrangement of detectors. The many instruments developed since 1972 can be grouped into three categories or generations according to data generation, collection, and scan time. Since image quality and scan time are closely interrelated, each reduction in scan time has increased the clinical usefulness of CT. Table 4 summarizes the equipment now in the marketplace according to this classification system. All models listed are now available for purchase, but are not necessarily in operation at this time.

Table 3. Evolution of CT technology, 1972 - 1977

Generation	Data generation, collection, and scan time[†]
First Generation	Single pencil beam and single detector with translation and rotation Scan time, 4 to 6 minutes
Second Generation	Multiple pencil beams and multiple detectors with translation and rotation Scan time, about 20 seconds
	Fan beam with detector array and rotational motion only Scan time, less than 20 seconds
Third Generation	Fan beam with fixed detectors and rotational motion only Scan time, less than 5 seconds

---

[†] Scan time is the time necessary to collect data for one tissue slice.

Table 4. Appearance of manufacturers and systems available

1973	1974	1975	1976
EMI[1]	EMI[1]	EMI[1,2]	EMI[1,2]
	DISCO (Acta)[2]	Pfizer (Acta)[2]	Pfizer[2]
	Ohio Nuclear[2]	Ohio Nuclear[2]	Ohio Nuclear[2,1]
	Artronix[1]	Artronix[1,2]	Artronix[1,2]
	Siemens[1]	Siemens[1]	Siemens[1]
		Neuroscan[1,2]	Neuroscan[1,2]
		General Electric[1,2,3]	General Electric[1,2,3]
		Philips[2]	Philips[2]
		Syntex[1,2]	Syntex[1,2]
		Varian[2]	Varian[2]
		Picker[2]	Picker[2]
			Am. Sci. & Eng.[2]
			CGR
			Hitachi
			G.D.Searle

[1] Head scanner
[2] Body Scanner
[3] Mammography

HEALTH PLANNING AND CT

The planning issues related to capital equipment purchases are complex. At least they include: efficacy, costs, cost-effectiveness, safety, reimbursement, distribution, utilization and obsolescence, which is related to the speed of technical development. Each of these issues is considered separately.

Efficacy

The question of efficacy of CT **brain scanning** for symptomatic patients has been basically resolved. Reviews by individual clinicians, the National Cancer Institute, the Office of Technology Assessment, the American College of Radiology, and the American Hospital Association agree that CT has a role in the diagnosis of cranial disorders.

One review of the clinical literature by the American Hospital Association summarized the accuracy of CT neurologic scanning. This review included the work of 13 clinicians who had scanned 3,687 patients between 1974 and 1976 (1,321 for intracranial tumors; 347 for cerebrovascular lesions including hemorrhage, infarct, and other cerebrovascular disease; and 2,019 for miscellaneous neurologic disorders). With one exception (52% accuracy for infarct diagnosis by one investigator) the diagnostic accuracy was between 85 percent and 98 percent (1).

CT **body scanning**, however, remains more controversial and as yet is not generally accepted by third-party reimbursers, health planners, and even some members of the clinical community.

Within the clinical community, new applications for CT body scanning and reports confirming early applications continue to be published. In addition, two comprehensive studies have just been completed. Last month, the National Academy of Sciences, Institute of Medicine, Special Committee Report on the Medical Efficacy of CT Body Scanning was published (2). This month, a review of clinical experience with CT body scanning using fast (less than 20 seconds) body scanners will be published by A. D. Little (3). The intent of this review was to collect and summarize:

Published clinical experience

Work presented at professional meetings:

1976, Spring American College of Radiology Conference
1976, Spring CT Conference, San Juan
1976, Radiological Society of North America, Chicago
1977, Spring CT Conference, Florida

The unpublished insights of leading clinicians.

Briefly, this review summarizes current clinical practice with emphasis on the experience at research centers discussing the known usefulness and uniqueness of the CT technique, as well as its limitations.

For example, CT body scanning (with the less than 20-second scanners) provides information unavailable from other diagnostic procedures for disorders of the pancreas; retroperitoneum; and mediastinum. Additionally, it is sometimes the primary tool and sometimes a confirmatory tool when used in diagnosis of liver disease.

CT is particularly important for the detection of metastatic disease in the liver and the lung. Other applications include kidney, adrenal glands, lymph nodes, other lung disorders, musculoskeletal system and the spine.

Without question, CT is most commonly used in tumor detection, differentiation, and staging. Detection of metastic disease and therapy monitoring are also very important. Other successful applications are radiation treatment planning and needle biopsy guidance.

On the negative side, CT has not been as successful in breast, heart, stomach, bowel, spleen, or in obstetrical examination. It certainly cannot compete with angiography for dynamic fluid flow studies or with traditional x ray for examination of broken limbs.

In sum, CT is another technique, which if used properly, should improve medical care. Clinicians at Mallinckrodt and Mayo have scanned more than 1,500 patients each and would agree that CT has a positive effect on patient management and outcome.

Cost and Charges

The cost of CT is the next most important issue after efficacy. Discussions of the costs of CT are filled with controversy. One problem is that everyone uses the same words and they all mean different things.

Several things are already clear--hospitals do not want CT to be a moneylosing venture, and health planners do not want CT to be a moneymaking venture. The question is, where is the middle ground?

Two cost and charge analyses by the Genessee Health Planning Agency and the American Hospital Association are summarized in table 5 (1,4). The components of costs are: (1) personnel, physician, and other (technicians, engineer, secretary), (2) direct expenses including service, insurance, power, supplies (tubes, film, and so forth), and staff training, (3) equipment least or depreciation, and (4) indirect expenses including administration, space, and so forth.

The charge per CT examination is set, supposedly to cover costs and reflecting the likely number of patients to be examined. For example, if 2,500 patients are examined at a charge of $150, total revenue is $375,000. If the charge is $200, total revenue would be $500,000. If these charges are compared with the costs in table 5, a hospital examining 2,500 patients per year and charging somewhere between $150 and $200 per examination is just breaking even.

Table 5. Costs and charges for CT

Category (costs per year)	Genessee Health Planning Agency	American Hospital Association
Personnel		
Physician	40%	--
Other (tech.; engineer; secretary)	12%	7%
Lease or Depreciation	34%	49%
Expenses, Direct		
(service, ins., power, supplies, training)	14%	12%
Expenses, Indirect		
(adminis., space, i.e., overhead)	--	32%
	$330,000	$364,000
Add indirect expenses	116,000	
	$446,000	
Add physicians fee @$35.00 for 2,500 scans/year		87,500
		$451,000
Charges for CT		
2500/year @ $150 = $375,000		
2500/year @ $200 = $500,000		

Cost-Effectiveness

The cost-effectiveness of CT has not been established conclusively. Some initial attempts have been published (5,6). Both of these deal only with brain scanning and do not include considerations of patient management and outcome. Although the data base for each of these studies is small, the conclusions in both are that CT offers significant cost savings.

To date two clinical groups have begun to study the cost-effectiveness of computed body tomography, Dr. Wittenburg at Massachusetts General and Dr. Evens at Mallinckrodt (7,8). Since clinical efficacy and cost-effectiveness are so closely interrelated, more work on the diagnostic accuracy of body CT and its impact on patient management and outcome will be needed before the question of cost-effectiveness is finally resolved.

We are about to undertake a cost analysis of CT, which at the very least will develop a methodological framework for evaluating cost-effectiveness and hopefully will provide more definitive information concerning this issue.

Reimbursement

Reimbursement is the key to Federal attempts to control the distribution and utilization of computed tomography. Generally speaking, charges for CT head scans are covered by third-party reimbursers if the CT purchase has been approved by the local health planning agency (through certificate-of-need or whatever other mechanism is being used). Although there is variation from State to State, most reimbursers still consider body scans to be in the realm of research, and, therefore, the charges incurred are not covered. (In Illinois, however, Blue Cross is reimbursing for body scans.)

The American Hospital Association report summarized the status of reimbursement practices as of mid-1976. Reimbursement practices vary considerably from State to State and from reimburser to reimburser (i.e., Medicare, Medicaid, Blue Cross, VA).

The National Academy policy study contains recommendations concerning reimbursement that we believe will be adopted (2):

"Reimbursement for CT Scanning:

* CT scanning of both the head and body when appropriately used for specified indications should be a covered diagnostic service under third-party reimbursement plans, accepting as criteria of efficacy the usual standards of clinical practice.

* Third-party payers should reimburse only for services provided by CT installations approved under a certificate of need program.

* Third-party payers should reimburse only for examinations approved under a utilization review program satisfactory to the payers.

* Third-party payers should continue to work toward eliminations if differences in coverage for ancillary services between inpatients and outpatients.

* A uniform cost-based method for determining the technical component of charges for all CT scanning should be established to eliminate excessive surplus or profit. This method should include amortization of equipment and remodeling costs over a minimum of five years and should be based on a minimum annual volume of 2,500 patient examinations and on actual use above that volume.

* Professional fees for the interpretation of all CT scans should be at a rate which eliminates excessive profits. A rate of $35 per patient examination is recommended at this time, unless special local conditions can justify a lower or higher rate. This charge may be subject to a modest adjustment for examinations involving the use of contrast material."

Obsolescence/Technical Development

In the past 5 years, many technical improvements in CT scanning systems have occurred. Retrofitting of systems with many of these improvements has been available for purchase. The price varies with the complexity of the update. For example, the cost of a modification to a computer algorithm may be less than $5,000, whereas the cost of a major instrument update, such as the substitution of a new generation scanning unit, may be as high as $75,000 to $200,000.

Several generations of CT scanning systems have been developed to date as previously described. As a result of these improvements scan time per slice has been reduced from 300 seconds to 2 seconds. With each shortening of the scan time, medical applications have increased. The next generation of equipment will probably reduce the scan time to milliseconds or be a gated system for cardiac use. However, it is not expected to be available for another 5 years. Therefore, the fast CT scanning systems currently available are not expected to become obsolescent within the next 5 years. Slower units still have significant applications in neurologic applications.

Planners' Priorities

In order to determine how we might most effectively assist local planning agencies as they decide when, where, and how many CT units should be installed, we surveyed every State and local planning agency in the United States including Alaska in January and February of 1977. Several questions were asked relating to the status of guidelines development, CT units now operational in their area, and so forth. Most importantly, we asked both local Health Systems Agencies (HSA's) and State Planning Agencies (SPA's) what factors they considered when evaluating a CT request. Their responses are summarized in Table 6.

Table 6. Factors considered by HSA's and SPA's when evaluating CT CON

Factor	HSA (percent)	SPA (percent)
Determination of Need	59	68
Personnel Available	37	46
Financial Feasibility (Cost)	35	37
State Guidelines Followed	28	22
Shared Services	18	17
Regional/Geographic Distrib.	12	20

Summary of Guidelines

As of the first quarter of 1977, only 22 percent (44) of the local planning agencies (HSA's) and 12 percent (6) of the State Planning Agencies (SPA's) had guidelines developed for the number of CT body units in their area. Whenever possible, we obtained a copy of any guideline for head scanners, body scanners, or both and attempted to summarize them in some consistent manner.

As is implied from the priorities stated by planners, most guidelines deal with:

Professional staff availability
Distribution
Need
Utilization
Area-wide requirements.

Professional staff availability requirements were simpler in the era before body scanning. To meet this portion of the requirement an institution needed a neurologist; a neurosurgeon and access to a neuroradiologist. The Missouri body scanner guideline requires--full-time--two certified radiologists, two x-ray technicians, and one each of an intra-thoracic, abdominal, and gynecological surgeon, a pathologist and an internist. New York City adds a urology specialist and multiplies every requirement by two. Most guidelines also include the need for a bioengineer--if not full-time, at least part-time.

Distribution. One of the specific challenges of Public Law 93-641 is to "distribute" care uniformly. That means that good medical care must be available to the total population. Planners are attempting to distribute scanners geographically within their region. Although some achieve geographic distribution to a greater or lesser degree, the attempt is being made, and it is a top priority.

To date, California, Florida, and Nevada have the highest per capita concentrations of scanners and they are the most unevenly distributed. Massachusetts has one of the lowest per capita number of scanners and they are the most evenly distributed.

Need. Brain scanning was justified on the basis of the activity of the neurologic service. It is generally accepted that a hospital can justify a CT brain scanner if it can be shown that 50 intracranial surgeries, 200 cerebral angiograms, 25 pneumoencephalograms, and 1,000 nuclear medicine brain scans are done per year.

For body scanning, such analogous procedures are not identifiable. One group has suggested that 5,000 nuclear medicine scans must have been done in one year. Many guidelines have required 24-hour emergency service by the scanner, and others have required a demonstration that there will be at least 50 percent outpatient utilization (Michigan). Another guideline requires that there be a minimum of 200 inpatient acute care beds (North Dakota). Simply stated, no uniform system for determining need for CT body scanners has been developed.

Utilization. Required utilization of CT varies considerably. The National Academy of Sciences recommends that every CT system in the area be doing 2,500 scans per year before another system is purchased to service that area (2). In CT guidelines, recommended utilization rates range from 1,500 patients to 6,000 patients with most of them being between 2,000 and 2,500.

Area-Wide Need. Determining regional need for CT services remains problematic and controversial. One of the approaches used is based upon population. The major flaw in this approach is that it does not reflect the real patient population served by major referral centers. Acknowledging that limitation, however, we have found the following published yardsticks in use:

Need for CT Scanners Based Upon Population

Massachusetts	1/600,000
Michigan	1/600,000
Alabama	1/250,000
New Jersey	1/300,000
Indiana	1/100,000

In our survey we found that most planners had concluded that one scanner was needed for every 300,000 in their region, regardless of what other measures had been used previously. In a sparsely populated region, more scanners are needed to provide equal access. Our recent review of the medical efficacy of CT body scanning leads us to believe that within the next 3 years at least one CT scanner will be needed for every 100,000 people to meet medical demand and need. Whether health planners will approve that many installations is unclear.

SUMMARY

In summary, when examining the current status of health planning and health planning as it relates to CT, one could say:

- The National Health Planning and Resources Development Act of 1974 is a broad-based powerful law.
- Control of Institutional Capital Expenditures is a small portion of Public Law 93-641.

- Health planning, planners and CT are here-to-stay and are becoming increasingly sophisticated.

- Health planning for CT is working.

REFERENCES

1. CT Scanners: A Technical Report. American Hospital Association, Chicago, Illinois (1977).

2. A Policy Statement: Computed Tomographic Scanning. Institute of Medicine, National Academy of Sciences, Washington, D.C. (1977).

3. Body Computerized Tomography (CT) Review of Clinical Experience. Arthur D. Little, Inc., Cambridge, Massachusetts (April 1977).

4. Genessee Regional Health Planning Council. Methodology Outline for Development of a Computerized Tomography (CT) Plan. (January 1976).

5. Wortzman, G., R.C. Holgate, and P.P. Morgan. "Cranial Computed Tomography: An Evaluation of Cost Effectiveness." Radiology 117:65-77 (1975).

6. Evans, R.G., and R.G. Jost. "Economic Analysis of Computed Tomography Units." American Journal of Roentgenology 127:191-198 (1976).

CONSIDERATIONS IN THE ESTABLISHMENT OF PERFORMANCE STANDARDS FOR COMPUTERIZED TOMOGRAPHIC SCANNERS

Roger H. Schneider
Division of Electronic Products
Bureau of Radiological Health, FDA

The advent and rapid propagation in recent years of special purpose x-ray systems employing x-ray transmission scanners to acquire attenuation data for reconstruction tomography warrants the intense scrutiny now being given these systems by radiological health and health planning agencies. All of the systems presently on the market incorporate digital computers for performance of the reconstructions and are generally referred to as computerized tomographic scanners or CT scanners. Barrett has demonstrated a system employing radiographic recording and optical analog reconstruction (Proceedings, IEEE, Vol. 65, p. 89-107, January 1977). Such a system is far simpler than those presently on the market and may bring about another revolution in this field. If such a system ever does appear in clinical form a new acronym for these devices will have to be found.

The task presently facing us at the Bureau of Radiological Health is the modification of the performance standard for Diagnostic X-Ray Systems and their Major Components, 21 CFR 1020.30, to minimize the radiation dose delivered to the patient by such a device while not compromising its medical utility. These devices are presently required to comply with the standard as written for conventional diagnostic radiographic and fluoroscopic machines. While this has presented no intolerable problems it is obvious that the standard must be modified to optimize its effect on this new class of products.

Today I will discuss some of the unique features of these products and some of the problems they present in the development of radiological performance standards.

All present systems use some form of collimation to obtain line-integral attenuation data in many views of the patient.

Figure 1 depicts a single source detector pair as might be used in such a system. Note the direction labeled "Z" for later reference.

Figure 2 depicts a so-called pencil beam rotate-translate system in which the source-detector pair translates along the entire width of the patient measuring the attenuation at each of many points. At the end of this traverse, the entire source-detector system rotates some small increment, generally on the order of one degree about the center of the patient and a new traverse is made. This process continues until 180° or so of arc have been covered.

Figure 3 depicts a modification of this and is called a fan beam, rotate-translate system in which the use of several geometrical rays from the source and several detectors permits rotation at larger angular increments between traverses, thus speeding up the entire process.

Figure 4 depicts a fan beam rotation only system in which the fan angle is large enough to encompass the entire section of the patient and the only mechanical motion is rotary.

Figure 5 shows a variant in which the patient is completely encircled by a stationary array of detectors and the source is the only moving element.

Fan beam rotation only systems are the fastest of those presently on the market requiring only a few seconds to acquire enough attenuation data for a complete reconstruction. There are systems under development in which the patient is completely encircled by detectors and a multiplicity of sources eliminates the need for any mechanical motion. These should provide the ultimate in speed.

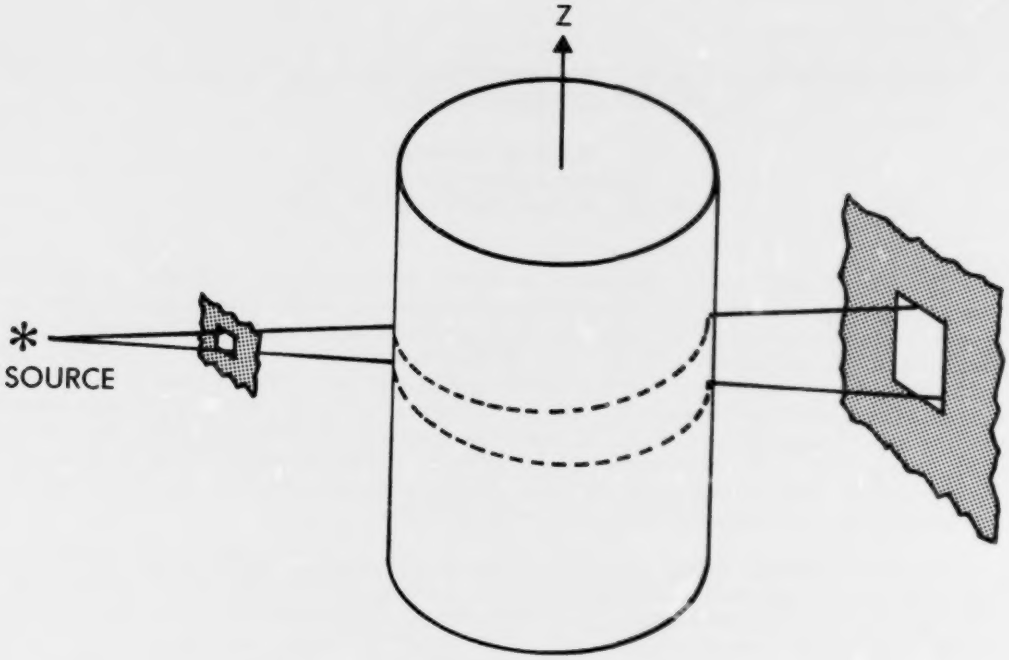


Figure 1. Source-detector geometry.

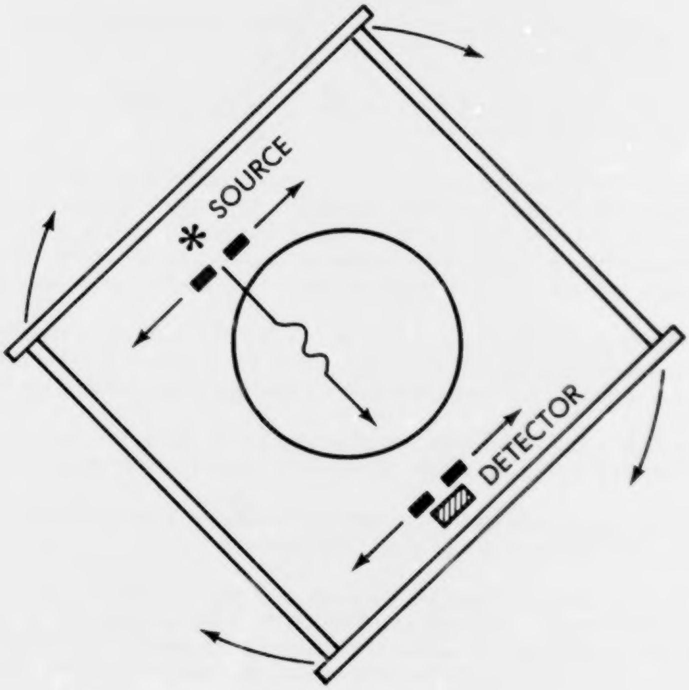

SOURCE
DETECTOR

Figure 2. Rotate - translate system.

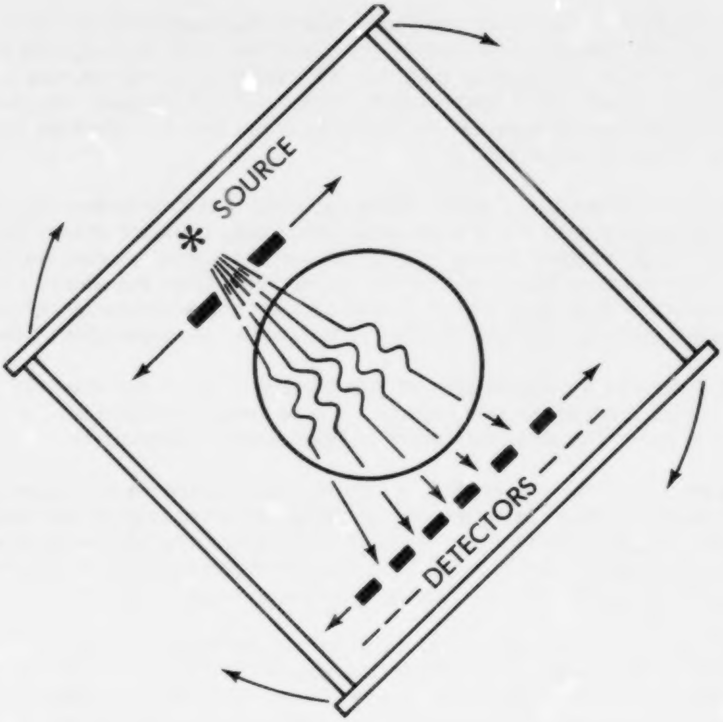

SOURCE
DETECTORS

Figure 3. Fan-beam rotate - translate system.

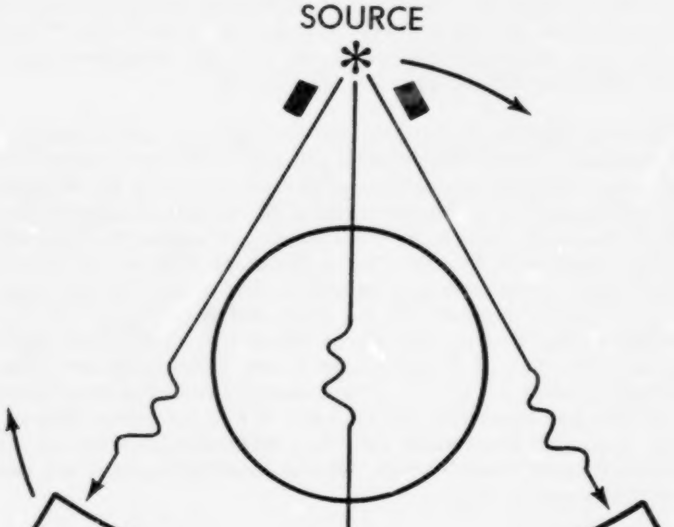

SOURCE
DETECTORS

Figure 4. Fan-beam pure rotation system.

One of the first problems we encounter in the development of performance standards for these wonderfully complex and various devices arises when we begin to study, in detail, the performance of the collimating system. Two types of x-ray sources are presently used, rotating anode, small focal spot sources typical of conventional diagnostic radiology and extended line fixed anode sources. As might be expected, the extended line sources pose the greatest difficulty in collimation.

Figure 6 is a schematic diagram of an early form of collimation of a line source system that does not comply with the present diagnostic x-ray standard in that the x-ray field in the plane of the image receptor measured at its 25 percent intensity points exceeds the size of the image receptor by more than 2 percent of the distance from the source to the detector. The resulting distribution of flux, in the Z direction and the discrepancy between the 25 percent intensity point and the 1 percent SID are illustrated at the right side of the figure.

Figure 7 depicts a complication of this system in which for the sake of expediency two detectors are exposed by the same source. The penumbra problem here is worse. Note the 11 mm region between the detectors which is irradiated but insensitive.

The large dashed lines indicate the extent of the penumbra as originally designed. If the two tilted vanes shown are inserted, the resulting penumbra is given by the small dashed lines. David Brown, Ph.D., Chief of our Medical Physics Branch, has calculated that insertion of these vanes has insignificant effect on the diagnostic performance of this machine and reduces the energy to which the patient is exposed by about 30 percent.

My purpose in discussing this was to illustrate the extreme importance of collimation in these systems, the small x-ray field dimensions which are involved, and the degree of difficulty that would be encountered in any attempt at precise measurement of the performance of such collimators. While possible but difficult under laboratory conditions it seems at present to be entirely impractical to address under field conditions, especially so when one considers the multiplicity of makes and models of machines, each having its own geometry and dimensions.

I would like to say a few words about the fundamental nature of the image that is created by such a device, and to expand a little on the concept of the "slice." To do this we need to look at a function that is occasionally referred to as the sensitivity profile (Brooks and de Chiro, Physics in Medicine and Biology, Vol. 21, No. 5).

Figure 8 illustrates the concept. Consider the points A and B located at some arbitrary position within a patient. Photons originating at any point along the source can pass through the point A and enter the detector aperture, thereby including the attenuation properties of the region surrounding point A in the line integral of the attenuating properties of the patient in this projection. However, only photons originating on approximately half of the source can pass through point B and enter the detector collimator. The net effect of this is a reduction in the weight given to the attenuating properties of the volume element surrounding point B in the computation of the CT number for the pixel which contains both A and B. Sensitivity profiles, expressed as fraction of the source which can irradiate a point and the detector simultaneously, as a function of displacement in the Z direction are given at the bottom of this figure as illustrations of the effect. The impact of this effect on the image is difficult to assess. Each point in the transverse section of the patient under view is viewed from many different angles, thus, also from many different distances from the source. As a result, the value of the sensitivity profile with which the many points in a pixel are weighted differs with viewing angle within a single scan.

This complicates the analysis and understanding of the effect called "the partial volume effect" illustrated in figure 9. Consider the small structure which extends up through the bottom of the section under view to the point "B" and has attenuation properties that differ slightly from the surrounding medium which is otherwise uniform. We ask ourselves the question, "What are the combinations of width of the structure, distance of penetration of the structure into the section, and difference in attenuation properties that will render this

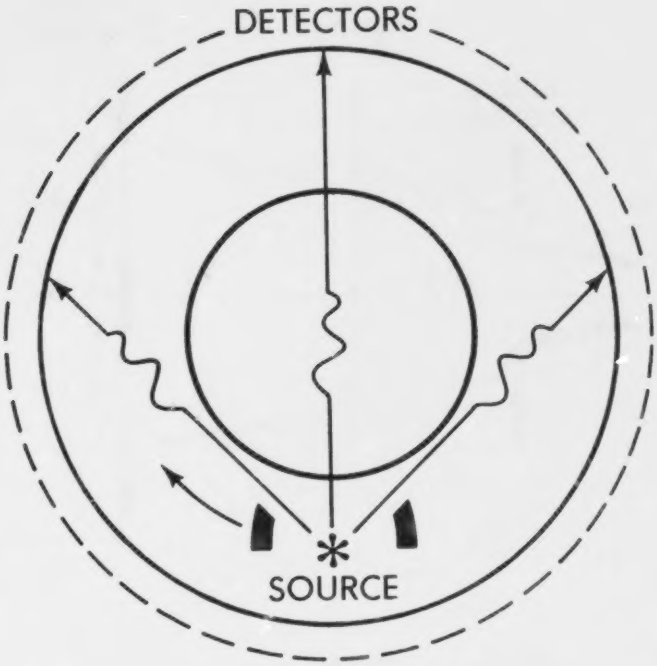

DETECTORS
SOURCE

Figure 5. Rotating fan-beam stationary detectors.

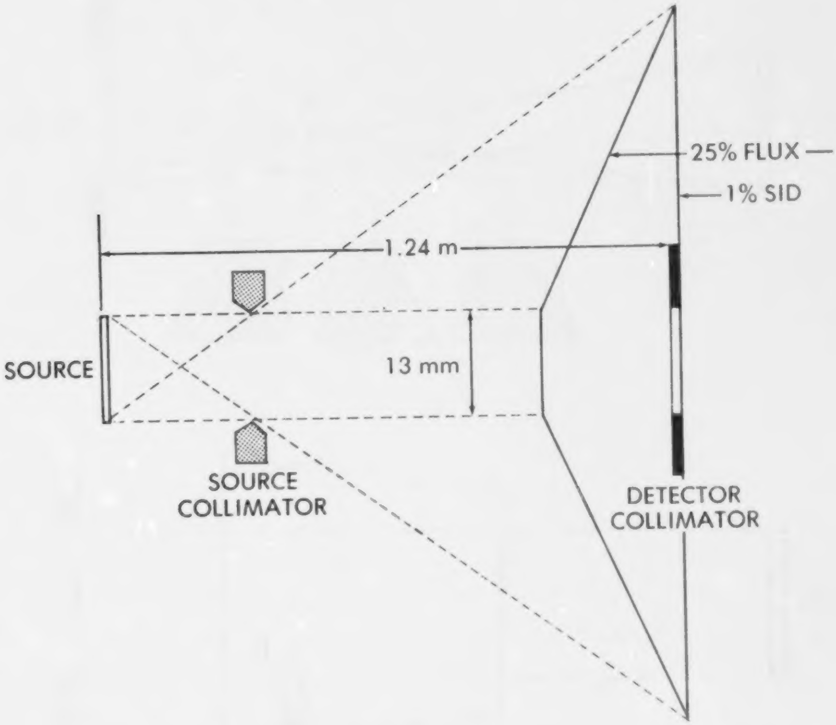

25% FLUX
1% SID
1.24 m
13 mm
SOURCE
SOURCE COLLIMATOR
DETECTOR COLLIMATOR

Figure 6. Noncomplying line source geometry.

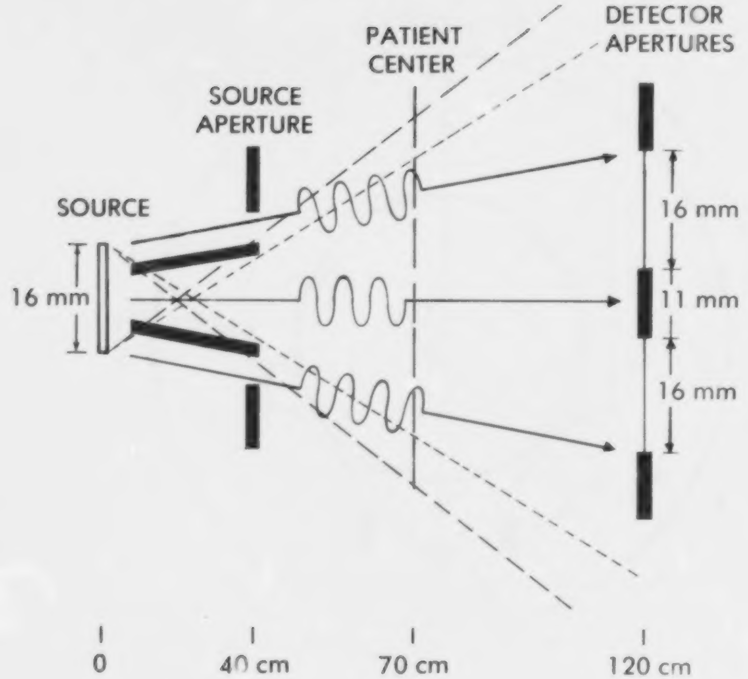

DETECTOR APERTURES
PATIENT CENTER
SOURCE APERTURE
SOURCE
16 mm
16 mm
11 mm
16 mm
0
40 cm
70 cm
120 cm

Figure 7

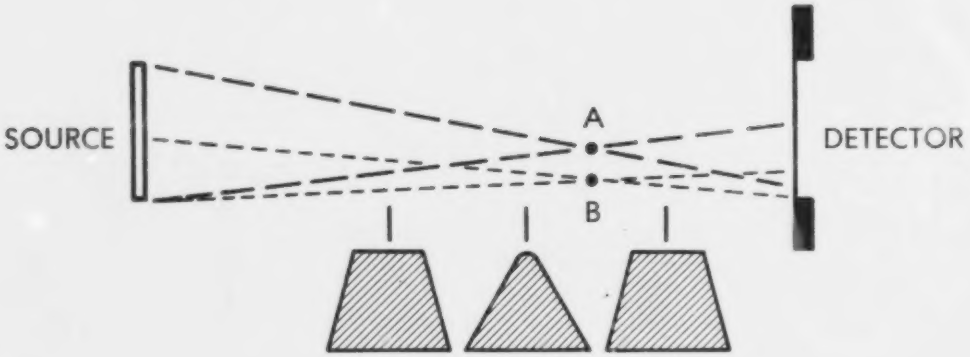

SOURCE
A
B
DETECTOR

Figure 8

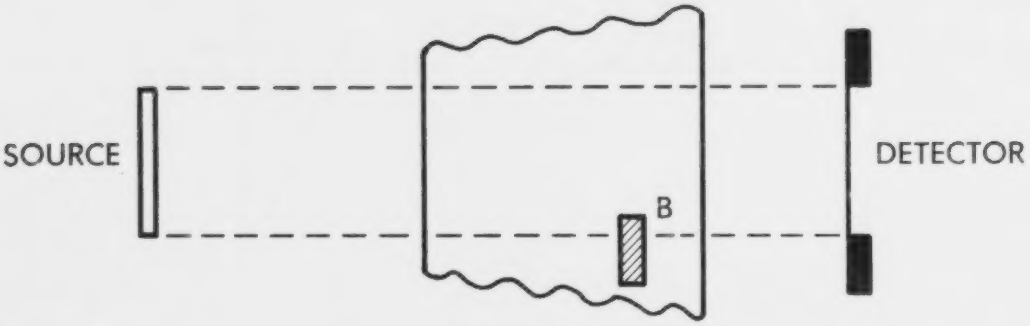

SOURCE
B
DETECTOR

Figure 9

structure just visible in the CT image?" As you might imagine, this is a question of considerable clinical significance, and there is at present no adequate treatment of it. Which brings us to the following conclusion.

It is deceptive to think of a CT image, normally referred to as a "slice" as a useful sample of a three-dimensional segment of the patient. It is a display of a section of a three-dimensional entity taken with a sampling function poorly controlled in the third dimension. The present informal concept of "slice," it seems to me, is baloney. What we have in a CT image is more nearly a true "cut," as if we had cut the patient in two and viewed the pieces "end-on." The sloppiness of our sampling function has a "dull knife" effect.

This has serious clinical implications when one considers such questions as, how many scans should we take, how far apart should they be? Spacing scans at a separation equal to the manufacturer's stated nominal slice width may, because of the nature of the sensitivity profile and the partial volume effect, result in failure to image existing pathology. Resolution of this matter will certainly be an important part of the development and evaluation of CT systems over the near-term. It is very likely that performance standards will have a role to play in this resolution. Our efforts on such questions within BRH are at present in their infancy.

It is worthwhile to mention one more aspect of CT use related to the sensitivity profile. Various groups, in the interest of improving the resolution in the Z direction, are subtracting data from several adjacent cuts spaced closely enough together to have significant overlap in their sensitivity profiles. Another procedure with some popularity is the collection of a large amount of data from many cuts at various displacements in an effort to make three-dimensional reconstructions. The radiological health impacts of such procedures are significantly greater than those of conventional procedures. The performance of machines that offer such options and ultimately perhaps even the efficacy of such procedures is a matter that deserves careful scrutiny by all parties concerned.

The Diagnostic X-ray Standard as presently written is a lengthy list of detailed performance requirements for the components of conventional radiographic and fluoroscopic apparata. This is the traditional approach in the field, and has proven to be both a practical and successful method of regulating this class of products. The Bureau is presently examining the feasibility of extending this approach to encompass CT devices.

There are several factors that make the development of detailed performance requirements for the subsystems of a CT device quite difficult. Consider the simple matter of collimation, which we examined earlier. It seems very difficult at this point in time to select specific numerical requirements for collimator performance that are defensible in a tradeoff between health protection and technical feasibility. Consider the variety of scanning geometries -what is the coupling between collimator performance and scanning geometry in determining health impact? It appears possible that the pattern we usually follow in the development of regulatory requirements, that of technical sparring with industry and ultimate compromise on something each will grudgingly accept may, when faced with a problem as complex as this, iterate infinitely, and ultimately collapse.

Suppose we were able to agree on some measure of acceptable beam size with respect to detector size? We are concerned here with beams that have spatial extent on the order of millimeters at distances on the order of a meter from the source. How would such beam sizes be measured under field conditions? Is it possible to develop a practical field method that can make such measurements across a reasonable fraction of the spectrum of variety in CT devices, with all their differences in geometry, all their detailed differences in dimension, and so forth? Consider the problem of x-ray field-light field congruence for conventional radiologic equipment, and the problems we have had with that. Are we really ready to start measuring CT beam size in the field? These are some of the questions we are wrestling with at BRH in our examination of various means by which the diagnostic x-ray standard can be amended to improve its treatment of these products.

The ultimate conclusion of our examination may well be that the conventional approach fails in the CT area and a new approach is needed.

Viewed in a certain light, CT systems pose an interesting contrast to conventional radiographic systems. In conventional radiography we have a simple system, geometrically static, with few components. A brief burst of photons from the source penetrates the patient and is recorded on a passive image receptor. The image produced is extremely complex, because of the superposition of anatomical features in the projection process and the complex transfer function of the image receptor. To have regulated such systems by comparing their imaging efficacy with the radiation dose delivered to the patient would have been impossible at the time the present diagnostic x-ray standard was promulgated. Only now are we beginning to complete our arsenal of analytical tools for quantitative assessment of the imaging performance of diagnostic radiographic systems. Computer controlled microdensitometers and sensitometric film processing facilities are not "field deployable" items.

In contrast, the CT system is a complex device geometrically, radiologically, and electronically. Specification of the detailed subsystem by subsystem performance may be far beyond our capability. However the output of such a device is exquisitely simple. It is a list of numbers, inherently digital, representing estimates of the attenuation properties of the object viewed relative to water. While the transfer function from exact attenuation properties to the numbers in the list may be complicated, non-linear, or imperfect in other ways, these numbers are intended to be quantitative estimates of the attenuation properties of the object, and most systems that have been studied approach that goal.

This immediately eliminates the problem of image quantification, which is the largest practical obstacle in the measurement of image quality in conventional radiography. There is no need for careful and tedious laboratory processing of a latent image. There is no need for an expensive and complicated instrument such as a microdensitometer. There is no need for careful measurement of a sensitometric function. Quantitative data is immediately available in machine compatible form. Such image quality measures as modulation transfer function, noise, and sensitometric scale can be applied directly without scientific defense of the image quantification process. The device, by its very nature, presents its output in measurable form.

Such image quality measures are related to the dose delivered by a CT device. Barrett has presented a fundamental analysis of the relationship between dose measures and the spatial sampling and quantum noise properties of CT systems (H. H. Barrett, S. K. Gordon, and R. S. Hershel, Comp. in Biology and Medicine 6:307 (1976)).

This might lead us directly to radiological efficiency requirements for CT products; i.e., limits on some measure of dose for various classes of image quality, considering spatial resolution, dimension of matrix, noise, modulation transfer function, or other parameters that are found to be meaningful.

What is the dose picture? In contrast to conventional radiography and fluoroscopy, for a CT system it is quite difficult to estimate the surface flux or exposure at each point because of the complex motion and geometry of the source.

Figure 10 is a schematic illustration representative of some types of machines. Notice the filter wedge, which is now between the source and the patient. This wedge may vary in thickness from a millimeter or less in the center to 20 or 30 millimeters on the edges--its function is to compensate for the cylindrical shape of the patient and reduce the dynamic range required of the detector. It rotates with the whole system but does not traverse with the source. Now the beam incident on the surface of the patient is varying in both flux and quality from point-to-point in a single traverse. This and other features make the estimation of the flux incident on the patient difficult to calculate and extremely tedious to measure. This makes detailed dose calculations difficult, either by conventional attenuation methods or by the more sophisticated Monte Carlo techniques that we have used in recent years. Even if the extensive and tedious measurements required to measure the incident flux on one machine were undertaken no assumption of generality for other machines, even of the same model, could probably be made.

Presently it seems that the only viable means of obtaining information on internal doses from CT systems is by experimental measurement of the doses themselves. BRH and the National Cancer Institute have undertaken a collaborative program to develop a phantom and protocol for the measurement of such doses and to conduct a field survey of various types of machines to look at variations from type-to-type (Fig. 11).

The phantom is a Lucite disc 12 inches in diameter and 2 inches thick with 25 holes in it. Into each hole is placed an insert holding 45, 3 mm x 3 mm x 1 mm chips of lithium fluoride, TLD 100 stacked as illustrated on the right hand side of the figure. When fully assembled, the phantom is sandwiched between two additional discs of Lucite, each of the same diameter and thickness. An example of the kind of data being obtained with this phantom is given in figure 12. This is the dose distribution in the "Z" direction at one of the dosimeter locations in the phantom. This distribution varies not only in intensity but also in shape from point-to-point in the phantom. Note that this is not the same as the sensitivity profile exhibited earlier. The sensitivity profile incorporates the restriction that all photons passing through the point must also enter the detector. The dose profile includes the impact of all photons including those whose direction does not intercept the detector.

In light of this, we may conclude that the question "what is the dose?" applied to a CT examination, is almost a meaningless question in the philosophical sense, because it has no useful unique answer. While it is true that the same situation applies in a strict analysis of conventional diagnostic radiography, the variation in dose within the patient is generally monotonic and such measures as average dose, dose at a particular depth, and so forth are accessible and useful. No small set of dose numbers meaningful for CT devices is yet apparent. For CT systems the meaningful question in the dose domain is "what is the dose distribution?" What is the practical impact of this? Must we use 300 to 500 TLD chips every time we test a CT machine, or is there a better way?

There are two important questions to be asked in an assessment of the health impact of a diagnostic radiographic procedure:

First: What are the organ doses associated with the procedure? That is, what doses are delivered to those organs with which radiation effects have been associated (i.e., breast, active bone marrow, thyroid, testes, and ovaries). This dosimetry is necessary to analyze the specific radiation risk of the procedure and to evaluate methods of reducing dose to these particular organs. This is the first order problem when sensitive organ systems are involved.

Second: What is the minimum radiologic insult to the patient that is consistent with the required image (diagnostic) information, regardless of the organ systems in the x-ray field? This implies (a) the optimization of image content per unit insult and (b) the avoidance of unnecessary absorbed dose, consistent with the assumption that any radiation carries with it some risk.

Obtaining an answer to the first question will require detailed examination of the use of CT, including both equipment design and clinical application. The second question is more in the domain of equipment performance. In essence, the less energy deposited in the patient, the better the radiation safety design.

The following remarks pertain primarily to the latter concept of dosimetry for CT systems.

What other measures then, that is, other than dose and dose distribution, might we consider for evaluation of the radiological impact of CT systems? A candidate is exposure in air at a point, for instance the point at the center of rotation of the system. An immediate objection to this is that it is not sensitive to variations in collimation which affect the flux beyond the physical limits of the measuring instrument and which can significantly affect the total energy delivered to the patient. This objection can be overcome by making the sensitive

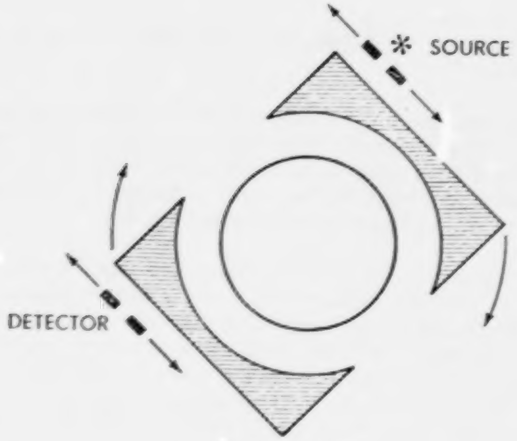

SOURCE
DETECTOR

Figure 10

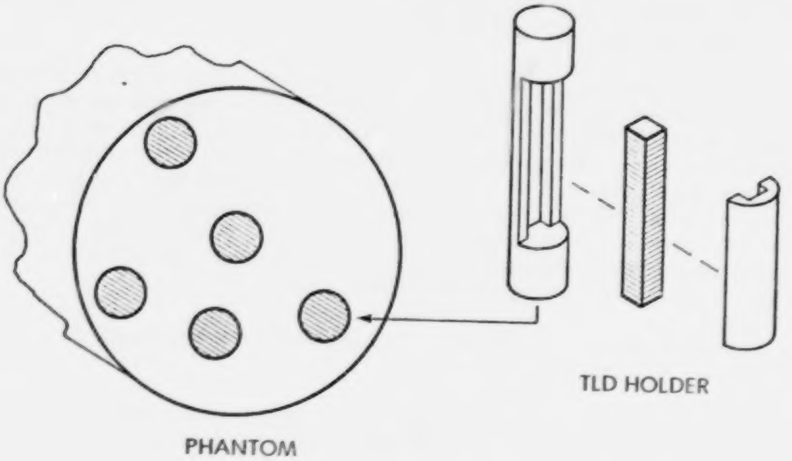

TLD HOLDER
PHANTOM

Figure 11

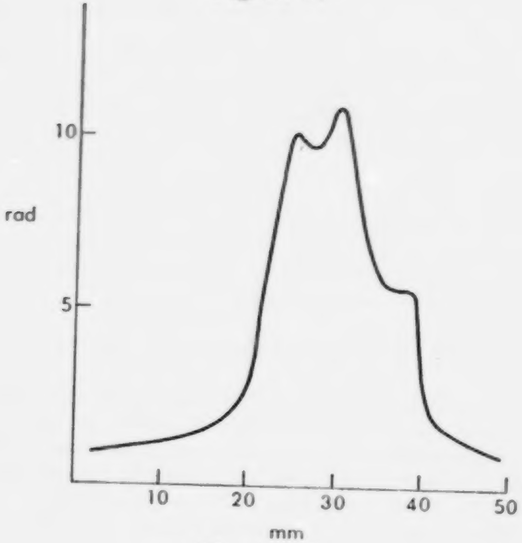


Figure 12

volume of the measuring instrument considerably longer in the Z direction than the thickness of any expected exposure distribution, thus making an integrated exposure, or roentgen area product sort of measurement. There are then left only higher order objections such as: the positioning of the instrument in the scanned volume may be critical, and the system may be insensitive to variations in spectrum which have a significant effect on the dose distribution. An example of such an instrument is given in figure 13.

A second candidate is dose in a phantom at a few selected points. The objections to this are the same as the first. It may be insensitive to opening up of the collimation and positioning may be extremely critical. A general objection to the class of local samples, of which both of the above proposals are members, is the questionable generality of any specific sampling scheme over the large variety of geometries in the population of all CT products.

Another candidate that suffers none of the above sorts of objections is integral dose; i.e., the total energy delivered to the patient. Under the linear hypothesis of biological effects of ionizing radiation, integral dose seems to be the radiation measure most directly relevant to the CT problem. It is a measure of the total risk to the patient, is linearly additive scan-to-scan, independent of scan spacing, and is completely insensitive to geometrical variations in the dose distribution, however wildly oscillatory they may be. In addition, it seems feasible to measure.

It could be measured with a phantom filled with a tissue equivalent liquid or plastic scintillator and viewed by photomultiplier tubes, or a large ionization chamber that was tissue equivalent in density of filling, as well as atomic composition. It could be measured by an instrument that consisted of an array of ionization chambers disposed within a tissue equivalent phantom, as indicated in figure 14. The axial length of the ionization chambers and the thickness of the phantom are sufficiently large to completely encompass the total width of any expected dose distribution. The number and disposition of the ionization chambers could be such as to adequately sample the dose distribution. The total charge collected in the ionization chambers is either summed directly or separately combined with appropriate weighting factors before addition or other processing. Such a device could be calibrated to measure integral dose.

The ultimate goal of the BRH-NCI collaborative study is to obtain enough information on the variety of dose distributions existing among the population of CT devices to permit us to design some kind of sampling scheme for a practical field test method that will adequately characterize the radiological impact of these products. Some kind of dose or exposure measurement integrated over the spatial domain seems the most likely result.

The solution to the regulatory dilemma may well have the form of a ratio between integral dose and information; in simplest form, a joule-per-bit limit. The compliance testing instrument could contain various targets to be imaged by the CT product during the radiation measurement process. If the instrument were connected to the CT machine to read and evaluate the images of these targets directly the value of the regulated variable could be computed on the spot. Certainly a factor to be considered here is some means of encouraging manufacturers to equip CT devices with a standard connector from which the images, in digital form, are directly available in a standard format to be machine read during the testing process as suggested by the digital connector in the figure. This might be coupled with some sort of simple visual image evaluation for verification.

The conclusion of our evaluation of the feasibility of the extension of the scope of the present regulations for diagnostic x-ray equipment to encompass tomographic scanners may be that a direct extension is not practical but that an immediate step in the direction of controlling the radiological impact per unit of information is necessary. I believe that we should welcome such a conclusion, and then ask ourselves, if, in light of the progress we have made in quantitative analysis of radiographic images in the past few years, there is any way in which a similar concept could be applied to conventional radiographic equipment.

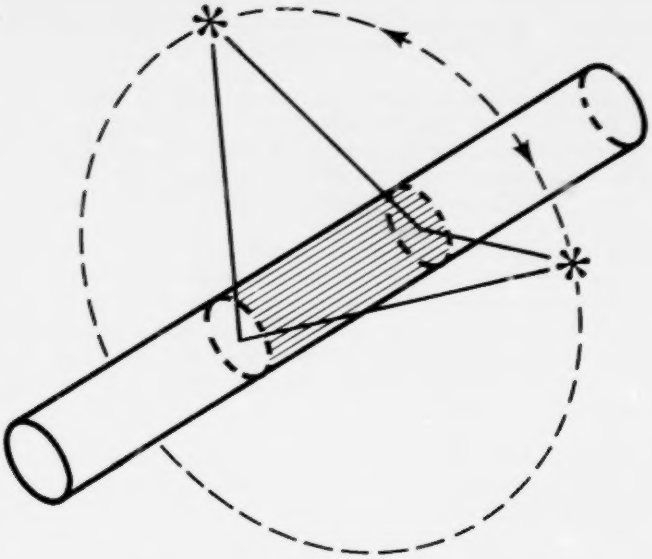


Figure 13

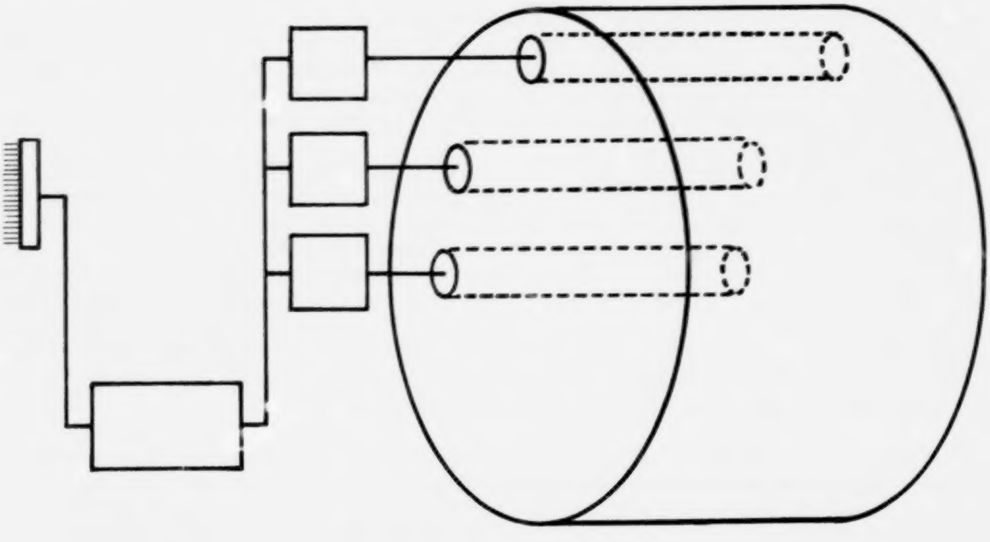


Figure 14

STATE RADIATION CONTROL CONCERNS

Gerald S. Parker
Assistant to the Commisioner (Radiological Health)
Massachusetts Department of Public Health

The CT responsibilities of the State Regulatory Agencies are much broader than Radiation Control. The States are also concerned about capital costs, annual cost, efficacy, cost effectiveness, yield, distribution of resources, and so on. The time allocated to me is too short to cover all of these items. Consequently, I will devote myself to only a few of them.

As of April 1977, there were more than 550 CT scanners operating in hospitals and private offices. Another 283 scanners had been approved or ordered, so that the total number of CT's available to patients will shortly rise to 850. California, with 140 scanners either approved or operational, has the most scanners, while Wyoming has the least - one. Now, why are the States oncerned?

1. Radiation Control people - If procedure is not efficacious, then people are being exposed to radiation unnecessarily.

2. Cost Control people - Unnecessary expenditure of funds, which leads to increased cost without benefits.

The magnitude of the problem is scary if one considers that there are 7,000 acute care hospitals in America. If 5,000 of these 7,000 hospitals were to purchase a CT scanner, the capital cost would be $2.5 billion, when using $500,000 as the average cost of the unit. If each machine does an average of 3,000 scans/year at an average cost of $270, there would be a cost of $3.5 billion to the medical care system. If 14 of 15 million people that would undergo this procedure gained nothing from it, then 28 million rads would have been absorbed with the biological consequences only to be determined some years hence.

Let us look at efficacy. The recently completed Institute of Medicine study stated, "...using current standards for evaluating clinical evidence, the committee finds CT scanning of the head to be efficacious at the level of diagnostic impact when used to diagnose and determine the effect of treatment on mass and structural lesions in or about the brain, including the meninges and orbit. Indications for a scan should include sufficient clinical information for determining the area of the head to be scanned and whether contrast should be used. CT scanning of the head is not an appropriate diagnostic procedure in the absence of strong clinical indications and supporting signs and symptoms."

Carrera et al. studied 85 patients who had headaches as their chief complaint. The patients were divided by whether they had normal or abnormal neurological examinations. None of the 53 patients with normal neurological examinations had abnormal CT scan results. Of the 32 patients with abnormal neurological examinations, 11 patients (34 percent) had abnormal CT scan results; 5 had tumors, 5 had degenerative lesions, and 1 had a subdural hematoma. The authors concluded that the 5 brain tumors and the subdural hematoma were potentially treatable structural abnormalities. The authors calculated that the cost of finding disease among the 53 patients with normal neurological exams at the 95 percent confidence limit was $4,363. However, as the authors point out, the 53 patients were examined at a cost of $12,720 without finding a single abnormality.

For the patients with abnormal neurological examinations as well as headache, the authors estimated that the mean cost of finding a treatable abnormality was $909, while the calculated cost of finding disease at the 95 percent confidence level was $500.

The above points out the importance of having medical protocols. The Institute of Medicine, as I mentioned above, stated that CT scanning of the head is not an appropriate diagnostic procedure in the absence of strong clinical indication and supporting signs and symptoms. In a recently completed survey, none of eight hospitals who had a scanner had medical protocols.

Banta and McNeill indicated that CT, in its early use, yielded about two-thirds positive findings, but recent data indicates that this figure has dropped to 50 percent, suggesting that it is being used more as a primary diagnostic tool (i.e. screening), rather than a secondary one. This again points out the necessity for medical protocols.

The OTA study claimed that efficacy should be questioned at four levels:

1. Technical capability - Does the machine perform reliably and deliver accurate information?

2. Diagnostic accuracy - Does use of the machine permit accurate diagnoses to be made?

3. Therapeutic impact - Do results obtained from the machine affect therapy planning and delivery?

4. Patient outcome - Does use of the machine contribute to improved health of the patient?

The OTA study claims that head scanning at the first level is efficacious. However, the report states, "Despite the generally excellent performance of CT scanners, there are some limitations to their technical capabilities." The problems are due to size of the objects, to small regions not being imaged or dually imaged, or to artifacts.

At the second level, there are beginning to appear a number of study reports. However, because of a large number of variables, the study claims that it is difficult to interpret the data on diagnostic accuracy in absolute terms, NCI is sponsoring studies on head scanning. The results will not be available for several years and will provide more definitive information than is now available.

At the third and fourth levels there is only sketchy information. Dr. Fineberg et al. in a study at Massachusetts General Hospital, indicated that treatment plans were changed in 19 percent of the patients scanned. There is presently no information available on the effects of CT scanning on patient outcome.

Although efficacy has been proven at the first level for CT scanning, there are still too many questions about overall efficacy to conclude that CT scanning is an effective modality; the two most important ones being effect on therapy and patient outcome.

I would like, at this time, to read a portion of a statement by Professor White of Johns Hopkins. Professor White addresses the question of efficacy in his statement.

> "Clearly, there has been a reduction in neurological diagnostic procedures, and I am told by the vice president of one major medical center that he has unemployed neurosurgeons on his hands! But if the EMI Scanner makes no difference to the outcomes for brain injuries, this should raise questions about the value of the previous diagnostic procedures. If neither contributes to improved outcome, why subject the patient to them and why allocate new resources to procedures that appear to make little difference?
>
> "In the United States 23 million people admit to having headaches annually; less than half of these consult a physician about them, generating about 16 million visits annually. About half a million persons are hospitalized annually with strokes, 270,000

> with head injuries and 6,300 with brain tumors. Of the latter, about 6,200 are malignant and current treatments are of only temporary benefit. For headaches as a presenting symptom, the EMI Scanner apparently provides no useful information other than to reassure the patient that there is nothing seriously wrong with his head. The EMI Scanner may help in the differential diagnosis of strokes, but to the best of my knowledge, there are not outcome studies published, although these could be quite easily and inexpensively conducted.
>
> "The United States will soon have about 1,000 EMI Scanners, with an annual capacity of over 5 million brain scans. This could amount to about one scan for every two persons with headaches, or to ten scans for every person with a stroke, to about 20 for everyone with a head injury, and to about 800 for everyone with a brain tumor. The capital cost of this equipment is about half a billion dollars; to this must be added at least another billion in health care expenditures of the country, namely, the difference between a 2 billion dollar bill for scans and the offsetting savings for other tests not done or shortened hospital stays. The real issue, however, is whether all of this makes any difference to the outcome of the patient's care. The EMI Scanner is a remarkable technological advancement; no question about it. But why does Britain have about four, perhaps a few more by this time, and why do we in this country, with a population four times larger, have 1,000? Who decided on what basis? Whose responsibility is it to determne whether a billion dollars is better invested in tests that apparently contribute little benefit to patients, even if it is painless and relatively risk-free, or whether this money should go into more biomedical research on the etiology of strokes, into behavioral research into the causes of headaches, or into the control of drunken driving that produces head injuries? Do you really want to pay for five million brain scans yearly, or for one out of every forty children and adults, from the public's funds, or even from private funds?"

There are many people who are beginning to agree with Professor White, that this is not a very efficacious tool as presently used. The yield is too low and costs are high.

Let us now look at Body Scanners. The Institute of Medicine Study concluded that whole body scanning is efficacious at the level of diagnostic impact, but that evidence was lacking at therapeutic impact and patient outcome levels. Therapeutic impact is defined as change in disease management that would not have taken place without the information from the scan. Patient outcome is defined as the effect of CT scan information on patient morbidity or mortality.

The OTA study indicated that body scanning had similar technical capabilities and limitations, as had head scanning. "The major difference is that patient motion poses more serious problems for body than for head scanning." There was limited information on diagnostic accuracy and no systematic studies on the therapeutic impact. There was no data on patient outcome.

The American Hospital Association report stated, "Early clinical reports on the use of CT body scanners indicate a high rate of success in confirming suspected lesions. However, body scanners are generally regarded as experimental devices and are seldom used in place of conventional diagnostic techniques."

The AHA study further states, "Evaluating the impact of CT on alternative diagnostic techniques is important, because claims of cost effectiveness of CT are based heavily on the prediction that it will replace other, costlier procedures. To date, CT has not fully replaced any alternative diagnostic technique. Hospitals must maintain and operate existing diagnostic equipment as well as the CT scanner, with utilization and resulting revenue falling off for some of the existing equipment. Thus the revenue generated from CT scannng services in a hospital may be needed by the radiological department to offset the fixed costs and operating costs of existing services and equipment that must be retained."

Illinois Blue Cross (November 22, 1976) and California Blue Shield (February 16, 1977) adopted a policy on what body procedures would be reimbursable. The list of procedures in these two reports, as well as the Institute of Medicine Report, are very extensive. It should be pointed out that the Illinois Group relied on "a group of radiologists," while the California Group relied on - 3 CT scanning specialists, professors of surgery and neurology and neurological surgery, internist, family physician, internist/oncologist and the industrial relations manager of the Ford Motor Company to make their policy.

As far as cost effectiveness of body scanning is concerned, Dr. Christie, at a 1976 meeting of the BRH Medical Radiation Advisory Committee, and the following to say, according to the minutes of that meeting:

> "Presentation by Dr. Christie. The presentation opened on the economics of the new CT (Computerized Tomography) systems. Dr. Christie used material perpared for a speech given at the Cleveland Clinic, prompted partly by the fact that it has often been stated that CT scanners will now give doctors a better opportunity to diagnose carcinoma of the pancreas. (All are aware that, once symptomatic, the cure rate for pancreatic cancer is zero.)
>
> "Using carcinoma of the pancreas as his model, and supplying standard data concerning incidence, survival, CT costs, etc., Dr. Christie calculated that the cost for surveying for cancer of the pancreas would be $319,000 for each case found, assuming all cases were found.
>
> "Furthermore, assuming that the 5-year survival rate for localized carcinoma of the pancreas is 4 percent, this would mean the cost for each person surviving 5 years would be about $620,000.
>
> "Extending the analysis to cancer of the breast, assuming screening of all women above 35 years, and that 5-year survival for localized disease would be achieved as a result of CT scanning, as contrasted to the expected average based on all stages of disease, then Dr. Christie estimated each 5-year survival would cost annually $200,000.
>
> "Thus, the total costs involved for surveys for breast cancer and pancreatic cancer would be about $10.6 billion, which would increase medical costs in this nation by 9.5 percent. This would increase survival in one in 11,000 people.
>
> "Dr. Christie suggested we need to look at costs whenever we decide to recommend any procedures".

However, the Institute of Medicine and the California and Illinois Blues concluded that CT of the pancreas was indicated at this time.

PROFESSIONAL CHARGES

The average professional charge in the country is thought to be $55. The Massachusetts Department of Public Health had recommended a professional charge of $30 18 months ago, while the recently concluded Institute of Medicine study had recommended a professional charge of $35.

As can be seen in table 1, a radiologist earning $50,000 should receive between $2.08 and $8.33 for the interpretation of each scan, while a radiologist earning $100,000/year should receive between $4.17 and $16.67/scan. Even allowing for the maximum time (20 mins.) and the maximum salary ($100,000/yearly) the average now being reported is more than 3 times what it should be. As a result of this type of an analysis, some have suggested that the maximum professional charge for interpretation of a CT scan should not be more than $10.00.

Table 1.

	5 mins./scan 60 mins./day 1 hour	10 mins./scan 120 mins./day 2 hours	20 mins./scan 240 mins./day 4 hours
Full-time equivalent based on 8 hour/day	0.125	0.250	0.50
$ 50,000 annual salary	$\frac{6{,}250}{3{,}000}$	$\frac{12{,}500}{3{,}000}$	$\frac{25{,}000}{3{,}000}$
Cost/scan	$2.08	$4.17	$8.33
$100,000 annual salary	$\frac{12{,}500}{3{,}000}$	$\frac{25{,}000}{3{,}000}$	$\frac{50{,}000}{3{,}000}$
Cost/scan	$4.17	$8.33	$16.67

TECHNICAL COSTS

The average charge for the technical component of CT examinations is $240, according to the Institute of Medicine study.

Table 2 indicates that it can be done for $87, if 3,000 scans/year are done and falls to $57/scan when 6,000 scans/year are done.

Table 2. Department's estimated economy of operation of scanner

	12 Patients/Day	16 Patients/Day	20 Patients/Day	24 Patients/Day
Fixed costs (monthly)	3000 scans/year	4000 scans/year	5000 scans/year	6000 scans/year
Assume $600,000 price 5 yr. lease (2.1%)	12,600	12,600	12,600	12,600
Room 500 ft.^{2} @ $10/ft·2/year	415	415	415	415
Power & light	300	400	500	600
Salaries: 2 techs	2,000	3,000	3,000	3,000
Secretary	750	1,500	1,500	1,500
Overhead @ 100% of salaries	2,750	4,500	4,500	5,500
	18,815	22,415	22,515	24,615
Variable costs for 12 patients/day				
Film - 264 packs polaroid @ $3.00	792	1,056	1,320	1,584
Chemicals & paper	150	300	300	300
	942	1,356	1,620	1,884
Total monthly cost	19,757	23,771	24,135	26,449
Maintenance contract	2,000	2,000	2,000	2,000
	21,757	25,771	26,135	28,449
Scans/month	250	333	417	500
Cost/scan	$87	$77	$63	$57

Table 3, which is taken from an American Hospital Association report, indicates another way of looking at technical costs. The average adjusted charge is $186.96, with the average cost $111--a net profit of $75. The profit, according to some, has been underestimated.

Table 4 is from a Connecticut report and indicates that the technical component cost could be as low as $62.25 if 3,000 scans/year are done.

Table 5 shows comparative costs by two different methods. According to Ron Evens, $129 would suffice if only 50 patients were done a week. The Health Science Management costs would be $99 when 56 patients/week are scanned.

Table 6 is a hypothetical cost model, as prepared by the American Association for Comprehensive Health planning. This figure indicates that the technical cost, at the 3,000-scan level, is $99, and at the 6,000-scan level is $67. The professional component is $26.67 at the 3,000 level and $23.33 at the 6,000 level.

It would appear that there is a tremendous profit both at the technical and professional level of CT, according to these tables. According to Dr. Thomas Meaney, in an editorial in the May 1976 issue of the American Journal of Roentgenology, "This level of profit has not gone unnoticed by commercial manufacturers who can calculate the large profits and are at least tempted, if not persuaded, to price their equipment, accessories, and modifications at a level where they will share in the 'retail profit'."

Dr. Meaney further stated in that editorial, "In my opinion, the only remedy to correct these temptations and put CT in proper perspective in the health care area is a realistic reappraisal of facts." According to the OTA study, Cleveland Clinic, with which Dr. Meaney is affiliated, did just that and reduced the total fee to $100.

Table 3. Example of income statement for CT equipment

	1st year	2nd year	3rd year
Revenue			
Gross revenue	$612,480	$612,480	$612,480
Bad debt allowance @ 12%	(73,497)	(73,497)	(73,497)
New Revenue	538,983	538,983	538,983
Expenses			
Direct expenses			
Salaries	$ 21,000	$ 23,000	$ 25,000
Maintenance (tube only in year 1)	2,000	25,000	27,000
Depreciation (5-year straightline on $600,000 cost)	120,000	120,000	120,000
Interest on $6000,000 @ 10%	60,000	48,000	36,000
Supplies and other variable costs:	45,552	48,741	52,152
Housekeeping, medical records, laundry and linen, plant operation, employee welfare, administration, and building depreciation			
Indirect expenses (plus 7% per year inflation factor)	$116,125	$124,254	$132,952
Total expenses	$364,677	$388,995	$393,104
Net revenue	$174,306	$149,988	$145,879

Table 4. Estimated annual operating costs for CT scanner

	1000 Procedures	2000 Procedures	3000 Procedures
Technical staff (salary and fringe benefits for two technicians and one sec.-recept.)	$ 36,000	$ 36,000	$ 36,000
Supplies (manufacturers' estimates)	5,000	10,000	15,000
Maintenance (contract: $85,000 for five years)	17,000	17,000	17,000
Indirect costs (estimated at 15 percent of direct costs)	32,250	33,000	33,750
Depreciation (straight-line depreciation of $420,000 capital cost over five years)	84,000	84,000	84,000
Insurance (manufacturers' estimates)	1,000	1,000	1,000
Total operating cost (excluding professional component)	$175,250	$181,000	$186,750
Operating cost per procedure (excluding professional component)	$175.25	$90.50	$62.25

Table 5. Comparative operational cost estimates for CT scanners

Item	Evens		Health services management	
Direct cost				
Fixed:				
Equipment	$ 77,400		$117,000	
Remodeling	3,860		10,000	
Maintenance contract	25,000		20,000	
Personnel	49,200		58,000	
New development	25,000		10,000	
Space upkeep	6,229		---	
		$186,689		$215,000
Variable (supplies)	37,960[a]		37,300[b]	
Total direct costs		$224,649		$252,300
Indirect costs	112,324		37,500	
Total cost		$336,973		$289,800

[a] Based on 50 patients per week.

[b] Based on average of 56 patients per week.

Table 6. Hypothetical cost model (based on 1975 cost levels)

	One machine						2 machine 2 shift
Scans per year	1,000	2,000	3,000	4,000	5,000	6,000	12,000
Direct variable							
Personnel ($12,92/ scan over 3,000)	$ 0	$ 6,840	$ 0	$ 12,920	$ 25,840	$ 38,760	$100,000
Supplies ($14,00 per scan)	14,000	28,000	42,000	56,000	70,000	84,000	165,000[9]
Power (40¢ per scan)	400	800	1,200	1,600	2,000	2,400	4,800
Maintenance (excess of contract)[5]	0	0	0	0	2,500	5,000	5,000
Subtotal	$ 14,000	$ 35,640	$ 43,200	$ 70,520	$100,340	$130,160	$274,800
Direct fixed							
Personnel [1c]	25,080	25,080	38,760	38,760	38,760	38,760	77,520
Equipment depreciation[4]	90,000	90,000	90,000	90,000	90,000	90,000	150,000[1]
Maintenance contract	25,000	25,000	25,000	25,000	25,000	25,000	50,000
Equipment retrofitting[6]	20,000	20,000	20,000	20,000	20,000	20,000	40,000
Insurance	1,000	1,000	1,000	1,000	1,000	1,000	2,000
Interest[11]	30,000	30,000	30,000	30,000	30,000	30,000	60,000
Subtotal	191,080	191,080	204,760	204,760	204,760	204,760	379,520
Total direct cost	205,480	226,720	247,960	275,280	305,100	334,920	654,320
Direct cost per scan	205.48	113.36	82.65	68.82	61.02	55.82	54.53
Indirect cost per scan[7]	41.10	22.67	16.53	13.76	12.20	11.16	10.91
Total facility cost per scan	246.58	136.03	82.65	73.22	66.98	66.98	65.44
Physician salaries (% time)	40,000 (25%)	60,000 (37½%)	80,000 (50%)	100,000 (67%)	120,000 (83%)	140,000 (100%)	200,000 (1 @100% 1 @50%)
Physician salaries per scan	40.00	30.00	26.67	25.00	24.00	23.33	16.67
Total costs per scan	$286.58	$166.03	$125.85	$107.58	$97.00	$90.31	$82.11

Example of Revenue Projections

Charges for scan with contrast
$257 less physician charge of $55 = $202 x .68% = $137.36

Charges for scan without contrast
$205 less physician charge of $50 = $155 x .32% = $ 49.60

Adjusted average charge $186.96

Revenues

13 patients per day x $186.96 = $2,430.48	Daily
$2,430.48 x 5 days $12,152.40	Weekly
$12,152.40 x 4.2 weeks = $51,040.00	Monthly
$51,040.08 x 12 months = $612,480.96	Yearly

FOOTNOTES

1. A. Personnel need for 3,000 scans per year

2.00 FTE	Technicians	@ 11,400 =	$22,800
.75 FTE	Aide	@ 7,600 =	5,700
.50 FTE	Clerical	@ 7,600 =	3,800
			$32,300
Fringe benefits @ 20%			6,460
Total			$38,760

B. The salaries are based on the average cost for 150+ bed hospitals in Southeastern Michigan as reported by the MHA/GDAHC compensation survey, March 1975 (+8% inflation to up date to March 1976).

C. "Personnel" is assumed fixed at a minimum of 3.25 FTE's with only the number of x-ray technicians as a variable below 3,000 scans per year. The importance of these assumptions is the belief that there is a certain minimum staff requirement (2.25 FTE's ultimate - minimum 3.25 FTE's at 3,000 scans per year).

2. Supplies include tubes, film, contrast media and other miscellaneous material. Several estimates have been made with an average of about $24,000 year for 3,000 scans. Recent data from local CT installations indicate a range from $10 to $23 with an average of $14 per scan.

3. Power is based on an estimated 40 cents per scan ($1,200 for 3,000 scans). A New York estimate was $1,000 for power.

4. Depreciation is based on straight line, 5 year life.

5. Maintenance contract of $25,000 per year is used as a fixed expense. However, for double shift usage, variable additions are added to reflect possible service experience ratings by the manufacturers.

6. Equipment retrofitting is included as an "amortized" fixed expense. in the three years since CT was introduced, improvements in scanning time have required the further investment of about $60,000 to remain current.

7. Administrative and general overhead (indirect) expense estimates have ranged from 10% to 60% of direct expense. A rate of 20% was chosen for illustration.

8. Cost of $16.67 per scan over 6,000 per year assumes the use of a highly paid technician at a salary of $20,000/year, in lieu of a fourth radiologist.

9. A supplies rate of $13.75 per scan is utilized at this level. This assumes a 3 percent volume discount.

10. Rather than a $180,000 (2 full units) level, $150,000 is used on the assumption that two machines would feed into a single computer unit.

11. Interest is based on a 5 year term on 75% of the capital cost.

RADIATION CONSIDERATIONS

The incident skin exposure during conventional neuroradiology has been estimated as follows:

1. Pneumoencephalograms 15-20 rads.
2. Cerebral arteriograms 15-20 rads.
3. Nuclear brain scanning 1 rad (it had been as high as 5-10 rads when it was first started).
4. CT scan - 2 10 rads with the great majority of scan being done at the lower end of the scale.
5. CT Body Scanning - too little information is available, but it has been estimated to be as high as 15-30 rads.

It was estimated that 100,000 cerebral arteriograms and 25,000 pneumoencephalograms were conducted during 1974. Assuming that all of these were replaced by CT Scanning (this, however, is impossible because there are limitations to CT), there would be a net reduction of incident skin exposure of 2,500,000 rads. However, this would be replaced by 30,000,000 rads if all headache patients were scanned. This would increase the absorbed dose by a factor of 12.

It is unclear what an average incident skin exposure of 2 rads would have on a population of 15,000,000. In light of other findings such as 6 breast tumors for every 1,000,000 women exposed at the 1 rad level, will 180 tumors now be introduced into the population because of the use of CT?

1. There is a very low yield from brain scanning and it will get lower as more units come on line.
2. There is a very high cost.
3. There is too much unnecessary radiation exposure.

Those three findings are the same ones that the Surgeon General found before he recommended against mass chest x-ray screening.

1. Low yield - Denver study 1965-1970; 276,598 x-ray yielded 54 active cases of TB. Cleveland study 1969; 109,000 found 18 cases of TB.

2. High cost - Denver; it cost $8,115 to find one active case by use of a mobile van. The average cost was $5,213.

3. The amount of radiation dose is not commensurate with the benefit gained, If, as in Denver, 276,000 are exposed to radiation and only 54 cases are found, then we have approximately 276,000 who have been unnecessarily exposed.

WHAT SHOULD BE DONE

Since it is clear that patients with only a presenting sympton of a headache will have a very low yield, therefore:

1. These patients should not be scanned;
2. For other patients, strict medical protocols must be prepared in order to restrict procedures to those patients with strong clinical indication and supporting signs and

symptoms. By restricting patients according to these protocols and refusing to CT headache patients, there will be a tremendous reduction in unnecessary radiation exposure;

3. The professional component must be reduced to a more realistic level of $10/scan for interpretations and $5/scan for supervision of the CT facility;
4. The technical component must be reduced to 90 if 3,000 scans/year are conducted and be adjusted downward if more than 3,000 scans/year are conducted;
5. Since body scaning is still in the experimental state, no further body scanners should be installed until the results of the studies now being conducted to determine if body scanning is efficacious are available.

In closing, I would like to quote from Dr. Hall's article, "Overutilization of Radiological Examinations." Dr. Hall is a practicing radiologist at a teaching hospital. "The final common pathway of the radiological examination is the radiologist. As with any other consultant, he has the right and the duty to refuse studies which are not clinically justified, particularly when they are potentially harmful. Along with this right and duty comes a new responsibility."

GENERAL SESSION

Moderator: *B. Jim Porter*, Louisiana

REPORT OF THE NATIONAL BUREAU OF STANDARDS' SURVEY OF STATE MEASUREMENT NEEDS
Elmer H. Eisenhower, Chief, Office of Radiation Measurement, National Bureau of Standards

TASK FORCE REPORTS

Moderator: *Alice Dolezal*, Minnesota

EVALUATION AND DISTRIBUTION OF RADIOACTIVE SOURCES AND DEVICES NOT MANUFACTURED UNDER THE ATOMIC ENERGY ACT
Edgar D. Bailey, Chairman, Texas

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAM
John W. Shaver, Chairman, California

NATIONWIDE EVALUATION OF X-RAY TRENDS
Beattie L. DeBord, Chairman, West Virginia

CREDENTIALING OF RADIATION ALLIED HEALTH OPERATORS
Donald R. Hughes, Chairman, Kentucky

SUGGESTED STATE REGULATIONS
Charles P. Froom, Coordinator, BRH

SUGGESTED STATE REGULATIONS: TECHNICAL REVIEW COMMITTEE
J. Dale McHard, Chairman, Oklahoma

SUGGESTED STATE REGULATIONS: PART C - LICENSING OF RADIOACTIVE MATERIAL
A. J. Hazle, Chairman, Colorado

SUGGESTED STATE REGULATIONS: PART K - NUCLEAR PHARMACY
Lynn A. FitzRandolph, Chairman, Arizona

NATURAL RADIOACTIVITY CONTAMINATION PROBLEMS
L. Hall Bohlinger, Chairman, Louisiana

RADIOACTIVE WASTE MANAGEMENT
Heyward G. Shealy, Chairman, South Carolina

ESTABLISHMENT OF SOIL CONTAMINATION LIMITS
A. J. Hazle, Chairman, Colorado

PUBLIC HEALTH IMPACT OF NUCLEAR MEDICINE PRACTICE
Phil Brunner, Chairman, Illinois

EMERGENCY PLANNING
Margaret A. Reilly, Chairman, Pennsylvania

Preceding page blank

NOTIFICATION PROCEDURES FOR RADIOACTIVE SHIPMENT
Leonard R. Solon, Chairman, New York

QUALITY ASSURANCE
Chuck Hardin, Chairman, Kentucky

MAMMOGRAPHY
Henry J. Bicehouse, Chairman, Pennsylvania

RADIATION MEASUREMENTS
Marshall Parrott, Chairman, Oregon

PERSONNEL DOSIMETRY
Larry Lloyd, Chairman, Montana

REPORT OF THE WORKING GROUP ON THE LEAK TESTING OF THE GENERAL LICENSE DEVICES OF 10 CFR 31.5
A. J. Hazle, Chairman, Colorado

REPORT OF THE NATIONAL BUREAU OF STANDARDS' SURVEY OF STATE MEASUREMENT NEEDS

Elmer H. Eisenhower
Chief, Office of Radiation Measurement
National Bureau of Standards

INTRODUCTION

Although the national program for radiation control is highly fragmented, with many responsibilities assigned to many agencies at the Federal, State, and local level, the authority for enforcing most of the regulations rests at the State level. Determinations of compliance with the maximum permissible levels of radiation to which the public may be exposed can only be made on the basis of measurements. For effective and equitable enforcement of regulations, these measurements must be made with sufficient accuracy and reliability. Uniformity of measurements is of primary importance for conformity between the regulator and regulatee. The probability that regulatory measurements will have to be defended in a court of law is increasing steadily. Therefore, the incentive to assure adequate measurement quality is becoming stronger. In addition, there is growing recognition that the overall effectiveness of any radiation control program is proportional to the quality of measurements which support it.

In recognition of these facts, a request for additional funding was submitted in 1972 so that NBS could provide increased services to State radiation control programs. In fiscal year 1975, limited funding was provided by Congress with the stipulation that initial efforts be directed toward a survey of measurement needs and capabilities in State programs. The survey was begun in Febraury of 1975 and was essentially completed in the summer of 1976. The purpose of this paper is to summarize the results of that survey.

SURVEY MECHANISMS

The prinicpal mechanisms of the NBS survey consisted of a comprehensive questionnaire and onsite visits to State program facilities. In addition, dialogue with members of the staff of various State programs served as a source of information. The last few National Conferences on Radiation Control were useful in this regard.

The questionnaire was prepared by NBS, and was reviewed and distributed by the Task Force on Radiation Measurement of the Conference of Radiation Control Program Directors. Responses were analyzed by both NBS and the Task Force.

SUMMARY OF VISITS

A total of 16 State programs were visited in the course of the survey. Those States visited are shown in table 1. No particular rationale was used to select those specific States which were visited. Some attempt was made to achieve a representative geographical distribution, and a few States were selected because of specific measurement problems that are common with a number of other States.

Table 1. States visited during the NBS survey

Arizona
California
Colorado
Florida
Illinois
Maryland
Massachusetts
New Jersey
New Mexico
North Carolina
Oregon
Pennsylvania
South Carolina
Texas
Virginia
Washington

Perhaps the most useful results of the visits were the general impressions that were obtained. Some of them are:

1. State radiation control programs have a major responsibility for ensuring public health and safety in the United States. The support received for operation of these programs is not commensurate with such a serious responsibility.

2. A surprisingly large fraction of the programs had recently moved, or were planning in the near future to move into new facilities. It is not clear whether this resulted from increased recognition of the importance of the program, or whether it was part of a general upgrading of State facilities.

3. The salary scales in State radiation control programs are generally too low to attract and retain highly qualified staff. The recent economic recession had a beneficial effect because competition was decreased. However, this advantageous condition is not expected to continue.

4. There is considerable variation of size, capability, resources, facilities, and leadership among individual State programs. The reasons for this variation are not always obvious.

5. An undercurrent of resentment and frustration toward Federal regulatory agencies and their regulations is apparent. This results partly from the large number of Federal regulators and resultant problems with overlap and inconsistency. Limited State resources could be used more effectively and efficiently if fewer Federal agencies were involved in promulgating regulations.

6. Attitudes toward the need for calibration of instruments vary considerably, but most States would like to have inhouse calibration capability. Experience with outside calibration services ranges from good to very bad.

7. Attempts at inhouse calibration of survey instruments have not been successful, because of lack of adequate radiation sources, instrumentation, and technical support. In essentially all cases, only one isotopic source is available for instrument checks.

8. There is a general expression of the need for more defendable measurements because of the growing possibility of challenge in court of law. For this reason, closer ties to NBS through measurement assurance programs are desired.

9. Interest in recommended procedures for environmental radioactivity measurements is high. This is particularly true for sampling procedures.

10. Those States that charge fees to help recover the cost of licensing and inspection appear to receive relatively high financial support. This is true even though the

fees do not generally go directly to the radiation control program, but into the State treasury instead.

In addition to these general impressions, useful information was obtained regarding specific measurement problems encountered in State programs. Since the purpose of this paper is to present survey results that are generally representative of State programs, specific problems will not be discussed here.

SUMMARY OF QUESTIONNAIRE

The questionnaire was prepared by NBS, and was reviewed and distributed by the Task Force on Radiation Measurements of the Conference of Radiation Control Program Directors. It was distributed to all 58 members of the Conference in March 1976. The last responses were received in May 1976, at the time of the annual meeting in Springfield, Illinois. A total of 34 States responded, plus 1 city (Philadelphia). Four responses were received from the State of New York. Thus the total number of responses is 38, which is considered to be satisfactory. Table 2 lists the States which responded.

Table 2. States that responded to the questionnaire

Alabama	Illinois	Massachusetts	Oklahoma
Arkansas	Indiana	Michigan	Oregon
Arizona	Iowa	Minnesota	Pennsylvania
California	Kansas	Mississippi	Rhode Island
Colorado	Kentucky	Nebraska	South Carolina
Florida	Louisiana	New Hampshire	Tennessee
Georgia	Maine	New Jersey	Texas
Idaho	Maryland	New Mexico	Washington
		New York	Wisconsin

The questionnaire consisted of two basic parts, one containing general questions relating to needs and preferences, and the other relating specifically to the types of radiation measured and instrumentation used. Some of the more significant results follow.

In response to the question regarding the order of importance of possible NBS services to State programs, the preference was indicated as follows:

1. Provide transfer standards to establish and maintain traceability to NBS primary standards.
2. Prepare standard procedures for calibration of field instruments.
3. Conduct periodic tests of measurement performance, and provide assistance if needed for improvement.
4. Prepare standard procedures for making accurate measurements.
5. Calibrate transfer standards periodically against NBS primary standards.
6. Conduct training sessions for State program personnel.
7. Provide technical assistance in evaluating measurement instruments.

8. Design a recommended calibration range for survey instruments.

9. Design a complete model State laboratory for radiation instrument calibrations.

Detailed information relevant to these preferences was obtained from subsequent questions. Regarding the types of transfer standards most desired, the order of priority is:

1. Calibrated radioactive sources.
2. Ionization chambers.
3. High-quality survey instruments.

Regarding standard procedures for calibration of instruments, the order of preference is:

1. Survey instruments
2. Counting systems
3. TLD systems

On the subject of measurement assurance programs (periodic testing of measurement performance) 32 of the 34 States responding indicated an interest in participation. In order of priority, the types of radiation measured in a measurement assurance program are:

1. Gamma (environmental)
2. Beta (environmental)
3. Alpha (environmental)
4. X (survey)
5. Gamma (survey)
6. Beta (survey)
7. Alpha (survey)
8. Neutron

The order of preference for standard procedures for making accurate measurements is:

1. X and gamma surveys
2. TLD monitoring
3. Environmental sample counting
4. Beta-particle field measurements
5. Dose calibrators

Regarding the degree of confidence that measurements presently made by State programs could be successfully defended if challenged in court, the average of responses fell almost exactly half way between "some could" and "most could." Only one respondent replied that "few could" and one replied that "all could." On a highly related question, all respondents except one felt that additional ties to NBS (such as a measurement assurance program) would make them more confident in defending their measurements.

In response to the question regarding preferred mechanisms that NBS could use to disseminate national radiation measurement standards, a clear majority selected a mobile facility for calibration of transfer standards (61 percent). The second most desirable option was utilization of a regional calibration laboratory (26 percent), and relatively few (13 percent) of the respondents preferred to have their transfer standards calibrated at the NBS laboratory site.

The most desirable method for calibration of survey instruments used in State programs was clearly indicated to be an inhouse capability. In fact, 32 out of 37 respondents (86 percent) selected this method as their first choice. Only 4 respondents (11 percent) chose an external service (commercial, university, or government) as their preferred method. With only one exception, return to the manufacturer was indicated as the least desirable method.

One of the questions expressed a desire on the part of NBS to begin working with a limited number of States in pilot programs aimed at gaining experience. Respondents were asked their degree of interest in participating with NBS in a pilot program. The results are shown in table 3.

Table 3. Interest in pilot programs

Degree of interest	Number of responses	Percent of responses
Very high	20	59
High	11	32
Moderate	3	9
None	0	0

An invitation to briefly describe major concerns (problems) regarding laboratory (environmental) measurements and calibrations of systems resulted in responses like the following:

- The inability to obtain radioisotope check sources in the concentration and activity levels normally encountered in routine monitoring.
- The lack of good reference data on; e.g., alpha, beta, or gamma self-absorption in materials such as milk, water, and soil.
- The lack of good standards for calibrating laboratory counting systems.
- The lack of standard sampling and measurement procedures for environmental monitoring.
- The inability to properly use new detection systems and techniques (e.g., TLD).
- The high cost of NBS calibrated sources.
- The lack of convenient calibration ranges or facilities or educational facilities for training laboratory personnel.
- The inability to separate and properly quantify ^{89}Sr and ^{90}Sr levels in liquid samples.
- Tritium counting in drinking water or water vapor.
- The determination of radioactivity levels (e.g., radon and radium) in phosphates.
- Determination of low level ^{131}I in milk by the procedure specified by NRC Regulatory Guide 4.3.
- Determination of alpha radiation levels in ^{226}Ra, ^{222}Rn, ^{238}Pu, and ^{239}Pu.

The next question asked how NBS could provide services that would help solve the above concerns and problems. The response was as follows:

- Issue standard procedures for analyzing environmental samples.
- Furnish a frequent, low cost calibration service for water and soil contaminated by natural or reactor generated nuclides.
- Provide detailed written procedures for:
    - (a) Preparation of gamma spectroscopy samples and alpha and beta self-absorption standards.
    - (b) Radon stripping for Ra-226.
    - (c) Sample handling, analysis and instruments calibration.
    - (d) Xenon gas measurements.
- Evaluate the presently available fluorescent liquids used for liquid scintillation counting.
- Provide guidelines for using the two most popular radioisotopes (^{137}Cs and ^{90}Sr) used for high energy beta calibrations - especially for those laboratories without anti-coincidence systems.
- Provide training for State personnel in environmental analysis. This could be done at the State or NBS laboratory.
- Provide a consultation service (i.e., hot line) easily accessible to State labs.
- Develop quality assurance procedures with details on:
    - (a) Calibrations
    - (b) Standard definitions
    - (c) Counting statistics
    - (d) Tolerance limits
    - (e) Minimum detectable activities
- Establish realistic costs for NBS radioisotope standards.

The questionnaire included a few questions about nonionizing radiation. Such measurements do not represent a major share of State efforts at this time, but this activity is expected to grow. The majority of respondents (86 percent) indicated they make measurements on microwave sources, primarily ovens. The next highest percentage of monitoring activity is for lasers (16 percent). At this time, not much interest was indicated in ultraviolet or ultrasonic radiation measurements. Regarding the kinds of services the States would like to see NBS provide for nonionizing radiation measurements, the priority is:

1. Guidance for instrument selection.
2. Training on use of measurement devices.
3. Calibration of microwave measuring instruments.

4. Periodic testing of electromagnetic radiation measurement system.

5. Calibration of laser radiation measuring equipment.

The second part of the questionnaire was concerned with the nature, use, and calibration of measurement instrumentation. There was a further subdivision into questions on survey instruments and on laboratory instruments. In the area of survey instruments, it was indicated that the majority of measurements are made on x-ray sources in the 50 to 250 kV range, at intensities from near zero to 100 mR/hr. This is because the first concern is leakage and scatter radiation. Although a question was asked about accuracy achieved and accuracy desired for such measurements, the results were inconclusive. As a result, the Task Force on Radiation Measurements will study the subject of accuracy requirements during the next year.

The subject of calibration of survey instruments is of substantial interest to NBS. As indicated by responses to the questionnaire, few survey instruments have a recent calibration that is traceable to national standards maintained by NBS, even under the most generous interpretation of traceability. In addition, there is no consistency among the States regarding frequency of calibration or the method used for calibration. Indications of the frequency of calibration of survey instruments covered the range from "at initial purchase" through "when suspect," "when returned to the manufacturer for repairs," "biannually," "quarterly," all the way to "daily." The latter response indicates rather strongly that, in common with the word "accuracy," there is some confusion about what the word "calibration" means. As to the method of calibration, the most-often used is inhouse with a calibrated source. The second most used is to send the instrument to the manufacturer, and the least popular method used is the private (commercial) calibration laboratory.

It is interesting to note that very few inhouse instrument calibrations are done using an x-ray source in the same energy region for which the instrument is normally used. This is one of the various discovered deficiencies summarized below:

1. The use of instruments that are uncalibrated or "calibrated" with radiations unlike those in which the instrument is normally used.

2. The lack of suitable secondary radiation standards in the States.

3. The use of instruments outside their normal design limits, particularly relative to energy response.

4. The almost total lack of suitable equipment and expertise in neutron measurements.

Laboratory instruments are considered to be those used to conduct analyses of environmental samples for detection of alpha, beta, and gamma radiation. The indicated number of samples analyzed per year ranged from 100 to 6,100 in various States. Most of them were in the form of water, milk, and air. The types of equipment used in State laboratories varied widely, and much of it was at least 10 years old.

Almost all counting of samples emitting alpha or beta radiation is done with proportional counters, and generally no energy determinations are made. Almost all gamma counting is done with scintillators, primarily sodium iodide. In the analysis of gamma-emitting samples, energy determinations are nearly always made, using pulse height analysis. Some of the better equipped laboratories use germanium detectors and high-capacity multi-channel analyzers. In some cases a minicomputer is used to aid in the analysis.

Thermoluminescence dosimetry is sometimes used for environmental measurements, generally by placing the TLD material near a suspected source of contamination and allowing it to remain for a specified time interval. Most States, however, indicated they did not possess TLD systems and some who have them have indicated difficulty in reliability of measurement results. Calibration of such systems is an evident problem.

Calibration of laboratory instrumentation generally involves use of a reference source or sources. These are available from NBS, EPA, NRC, or several private companies. In many cases such reference sources are used to calibrate counting systems before every use or at least once daily. Using this system of calibration, it is relatively easy to identify an unknown qualitatively at least. Quantitative determinations involve additional considerations such as counter efficiency and self-absorption for a particular sample. Efficiency of the detector system is not easily determined except for the simple case of a point source in a well-known geometry. In most practical measurements, this is not a typical counting arrangement.

Because the measurements are made at levels barely above background, there is a problem of knowing if the results are statistically significant. This is a relatively difficult problem that requires expertise that is not readily available to State programs.

PERCEIVED NEEDS

In March 1977, the Task Force on Radiation Measurements completed its report of measurement needs from the State program perspective. In summary, the recommendations of that report are (not in priority order):

"1. There is a need for more direct NBS assistance to the States in the areas of physical standards and measurement systems for radioactive materials and ionizing radiation. In particular NBS should develop a mobile calibration laboratory to assist the States in both quality assurance and training.

"2. NBS should provide more standard reference sources directly to the States at little or no cost.

"3. NBS should review and approve all Federal guidelines, standards, and regulations that require radiation measurements prior to the promulgation of such guidelines, standards, and regulations to assure that such radiation measurements are both technically feasible and practically attainable.

"4. NBS should coordinate the development of model sampling procedures, chemical separation procedures, and analytical measurement methods for a variety of environmental radiocontaminants which could be used by all State, Federal, and private laboratories to assure consistency in the quality of measurements.

"5. NBS in cooperation with EPA should be designated as the Federal agency responsible for coordinating efforts among the Federal and State agencies to immediately develop a uniform data reporting system so that present environmental data which is being generated throughout the country can be utilized and evaluated in terms of possible population exposures.

"6. NBS should design a model calibration facility and recommend procedures for calibration of field ionizing radiation survey instruments and monitoring systems.

"7. There is a need for additional training for all State personnel involved in ionizing radiation measurements. Training programs should be sponsored and supported by all Federal agencies involved in ionizing radiation measurements. It is recommended that The Conference of Radiation Control Program Directors establish a Task Force on Training which would, as part of their efforts, coordinate the training activities sponsored by Federal agencies.

"8. NBS should begin to work with specific States to resolve specific measurement problems which could be applicable to the remaining States. Such areas may include the design and operation of a State calibration facility, calibration of specific instruments for specific types of measurement problems, and so forth.

"9. The present Environmental Protection Agency environmental radioactivity laboratory intercomparison studies program provides a cross-check on individual laboratories. That program has been very successful in identifying specific problems. However, there is presently no followup program to provide assistance to those laboratories which the cross-check program identifies as having such problems. The Task Force recommends that the Environmental Protection Agency, the Nuclear Regulatory Commission, the Energy Research and Development Administration, and the National Bureau of Standards cooperate in resolving this issue.

"10. The Task Force was only able to scratch the surface of the problems. It is believed that a more in-depth analysis would be appropriate and may alter the above recommendations. Therefore, as a final recommendation, the National Bureau of Standards should continue to sponsor the Task Force on Radiation Measurements in a manner suitable to both the National Bureau of Standards and the Conference of Radiation Control Program Directors."

Perception of State program needs from the NBS viewpoint must be conditioned by the boundaries imposed on NBS by its legislative authority. The primary NBS functions are (1) development and maintenance of the national standards of measurement, (2) provision of means and methods for making measurement consistent with those standards, (3) the determination of physical constants and properties of materials, (4) the development of test methods and actual testing of materials, supplies, and equipment, (5) cooperation with other government agencies and with private organizations in the establishment of standard practices, incorporated in codes and specifications, and (6) advisory service to government agencies on scientific and technical problems. Thus the strongest consideration must be given to those needs concerned directly with standards, their dissemination (usually in the form of calibrations or reference sources), and measurement assurance activities. In addition, the development of standard practices such as those prescribed in voluntary standards must be given strong consideration. Needs that do not fall into these areas of primary consideration must, of necessity, be considered in a secondary manner.

PROGRAM PLANS

Development of an NBS program that is responsive to State needs must be guided by the NBS functions stated above, as well as the restrictions imposed by limited resources. At this time, approximately 3 man-years of effort can be devoted to these tasks. This will not allow us to develop a comprehensive program, but will enable the initiation of a limited number of pilot programs. From these limited efforts we hope to develop a foundation for future expansion.

Perhaps the clearest need discovered in the study relates to calibration of survey instruments, particularly those used for measurement of x and gamma radiation. This represents an area of major concern to State programs, as indicated by the questionnaire and the Task Force report. Consequently we are beginning a pilot program with the State of Illinois to establish an inhouse calibration capability in that State program. Originally the pilot effort will concentrate on development of a calibration facility in the 50 to 120 kilovolt range, with exposures from 100 mR to 1.5 R. This is the area of interest for enforcing the Illinois regulations relating to maximum exposures of patients during x-ray diagnostic procedures. Essentially all the other States also have an interest in this area and the experience gained though this pilot program should have wide application. In addition, the Illinois calibration facility will be available to serve the needs of the surrounding States as a regional laboratory. This will be an interesting test of the concept of having a State laboratory serve as a regional facility.

In the area of laboratory analysis of environmental samples, we have begun to coordinate a project which has as its purpose to "establish more standardization in data reporting conventions including the definitions of detection limits and the treatment of results at or below these limits." This activity is consistent with the recommendations of the Task Force report. On June 7, the first meeting was held of the subcommittee formed to address the problem. At this time, the subcommittee membership includes representatives of the States, a utility, a contractor, NRC, ERDA, HASL, EPA, HSL (Health Services Laboratory in Idaho Falls), and NBS. Subtasks have been assigned to the members, on the specific subjects of confidence level, random and systematic errors, units, detection limits, and significant figures. Assuming a consensus can be achieved, the recommendations of this subcommittee will be of value to all State programs. This project is one of nine that are included in the overall program of the Steering Committee on Upgrading the Quality and Usability of Environmental Radiation Data, sponsored by the Health Physics Society.

A third pilot program is concerned with field measurements of low-level environmental radiation. In response to a request from the State of Florida, we are beginning a project that will lead to the construction of a distributed calibration source for instruments used to measure gamma levels in the vicinity of 10 R/hr. This particular level is of interest because of the current EPA interim recommendations for gamma exposure levels at new structure sites on Florida phosphate lands. A distributed calibration source is desirable because large errors may result if a point source is used to calibrate instruments that measure distributed sources. Experience gained in this project should be generally applicable in States where phosphate or uranium mine tailings present problems.

Other pilot programs will be added if possible within our resource limitations. Needs in State programs will continue to be studied in greater detail, and adjustments in NBS activities may be made as the result of further studies.

CONCLUSIONS

Although the NBS survey provided answers to some questions, it also resulted in raising other questions that must be resolved in the near future. Some of them involve policy decisions that must be made by various organizations or institutions. These decisions relate to limited resources at the State and NBS level, incentives for calibrations and measurement assurance, cost recovery for NBS services, and the economic viability of calibration laboratories. Although nearly all States want the capability for inhouse calibrations, relatively few are in a position to make the necessary investment of funds. As an alternative, regional calibration laboratories can be considered, but there is no assurance that such facilities would be fully utilized, especially if operational costs must be recovered on a fee basis.

It would be highly desirable to have a mobile NBS calibration facility that would visit State programs periodically to provide calibrations, measurement assurance tests, and training. Past attempts to obtain funding for such a facility have been unsuccessful, partly because it would represent too much Federal involvement in the form of long-term financial support. As a result, other methods must be sought to provide necessary services to the States at lower costs to the federal government. Various alternatives will be studied during the next few years, and detailed interactions will be required with the States during this period. The Task Force on Radiation Measurements will be extremely useful for this purpose. Through continued cooperation and mutual support, further progress will be made.

TASK FORCE NO. 1

EVALUATION AND DISTRIBUTION OF RADIOACTIVE SOURCES AND DEVICES NOT MANUFACTURED UNDER THE ATOMIC ENERGY ACT

(Commonly Known as the NARM Task Force)

Edgar D. Bailey, Chairman - Texas
Allan C. Tapert, Secretary - BRH
James A. Blackburn - Illinois
Eddie S. Fuente - Mississippi
Kirk Whatley - Alabama
Edgar C. "Jim" Ashley - NRC
Walter Cool - NRC
Joseph E. Fitzgerald, Jr. - EPA
Charles P. Froom - BRH
Donovan A. Smith - NRC

At the 8th Annual Meeting in Springfield last year, Task Force No. 1 reported to the Conference that 12 NARM Guides for specific products and an introductory guide, which explained how to use the other 12, had been written by the Task Force and that hopefully they would be published within the next few months.

In July 1976, the Task Force met in Austin, Texas, to review the comments that had been received since our last meeting prior to the Springfield meeting. Following the Austin meeting type was set and "manuscript" copies of the NARM Guides were prepared and distributed to the Task Force members and the Federal resource people assigned to the Task Force.

On November 11, 1976, the Chairman of the Task Force wrote the Chairman of the Conference stating that the Task Force was satisfied with the NARM Guides, requesting that the Conference Chairman seek the final concurrence of NRC, EPA, and BRH with regard to the guides, and asking for Conference authorization to publish the NARM Guides.

On January 31 and February 1, 1977, the Task Force met in Atlanta, Georgia, to discuss future work for the Task Force. At this meeting the Task Force was given a letter prepared for John C. Villforth's signature and a letter signed by William D. Rowe. These letters were in response to the Conference Chairman's letters requesting review and concurrence by these Agencies. The Task Force reviewed these two letters and made minor changes in the NARM Guides.

On February 11, 1977, the Chairman of the Task Force wrote to the Conference Chairman stating that these two letters had been considered and again asking for authorization to publish the NARM Guides.

Since February the publication of the NARM Guides has been stymied by events and questions totally outside the Task Force's capabilities to resolve. The Task Force has felt that the NARM Guides were ready for publication since the end of its July 1976 meeting. Their publication is pending awaiting the resolution of certain non-technical questions by the Conference Executive Committee, BRH, EPA, and NRC. Hopefully such resolution will come in the very near future.

RECOMMENDATIONS:

Task Force No. 1 recommends:

1. That the presently prepared NARM Guides be published immediately.

2. That the Task Force be continued in the next year and charged with the responsibility for preparing the following additional NARM Guides.

    (a) Information for the Assessment of the General Population Dose from Consumer (Exempt) Products Using the CONDOS Methodology.

    (b) Guide for the Inspection of Manufacturers and Distributors of NARM Products (Quality Control).

    (c) Criteria for Granting of Extended Leak Test Intervals for Sealed Sources Containing NARM.

    (d) Suggested Standard Licensing or Letters of Authorization Conditions for Manufacturers and Distributors of NARM.

3. That the Task Force be charged with the responsibility for reviewing the Medical Device Act and preparing informational statements and guidance on the respective roles of the individual States, the Conference, BRH, and the Bureau of Medical Devices with respect to NARM and other radioactive materials.

4. That the Task Force meet at least annually hereafter solely to consider comments and recommendations related to the use and implementation of the NARM Guides and to make needed amendments to the NARM Guides.

TASK FORCE No. 2
CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAM

John W. Shaver, Chairman - California

The following is submitted in response to a request from the Healing Arts Council to report on the activities of the Task Force.

CHARGE

Task Force No. 2, Part A was assigned the charge of developing criteria that can be used to evaluate the adequacy of a State x-ray and nonionizing program. In carrying out this assignment, the Task Force was reminded to consider mechanisms that would ensure compatibility among Federal and State programs in the enforcement of radiation protection standards and regulations.

MEMBERSHIP

The Executive Committee appointed John Shaver, University of California at San Francisco as Chairman and Simon Kinsman, Past Chief of the California Radiologic Health Unit, and Jim Hickey, Rhode Island, as members. Richard Gross, Bureau of Radiological Health, and DeVaugh Nelson, Environmental Protection Agency, were assigned as Federal resource persons. Mr. Charles Showalter has met with the Task Force representing Mr. Gross. In addition, Bobby Dillard, FDA Region VII and Warren Jacobi, Colorado, have met with the Task Force during its only full meeting. Mr. Shaver and Dr. Kinsman met with Messrs. Morgan Seale and Dale Stevenson, FDA Region IX and Mr. Robert England, California, to obtain their views regarding this assignment.

MEETINGS

The Task Force met April 26-27, 1977, in Denver, Colorado. This report is based upon the results of that meeting. All members were present except Dr. Nelson and Mr. Gross, who was represented by Mr. Showalter.

HISTORY

Workshop No. 1 at the 7th Annual Conference in Hyannis, Massachusetts was charged to consider the development of criteria for an adequate State Radiation Control Program. In its report to the Conference, it recommended the formation of a Task Force to further study this matter. In September 1975, the Executive Committee implemented this recommendation by forming a Task Force; however, funds were not available for support. In September 1976, the Executive Committee decided to reactivate the Task Force. In December 1976, the charge was clarified and funds were allotted to hold four meetings. As reported above, the Task Force has held one meeting.

BACKGROUND

The problem of developing suitable program criteria has surfaced on numerous occasions and has been given considerable attention by the Bureau of Radiological Health, Nuclear Regulatory Commission, and selected States. For example, in 1969 the BRH prepared a detailed questionnaire as part of a study to evaluate the status of State radiation control programs. The questionnaire was carefully developed with input from States, regional offices, and other Federal agencies such as the AEC. It was pilot tested in most regions, and revised and improved based upon those tests.

Other work in this area includes the sending of Federal and State survey teams upon request to selected States to conduct detailed program evaluations. The Atomic Energy Commission has developed detailed criteria to evaluate Agreement States to ensure program compatability. In 1972, the Southern Interstate Nuclear Board conducted a study of Radiological Health Programs in the South. The Conference has formed workshops to consider this matter. The Task Force has taken full advantage of this previous work.

DECISIONS

Following a careful review of available materials, the Task Force decided the following:

1. The charge could be best implemented by developing a comprehensive list of criteria to be used by State Program Directors. The criteria should reflect the needs of a comprehensive program and should be detailed enough to assess staffing and funding needs, but flexible enough to account for the wide spectrum of individual State needs and resources.

2. Program Directors should compare their program with these criteria to determine deficiencies or weak areas. Upon identification of weaknesses, a Director can point to the deviation from nationally accepted criteria to add support to justifications for budget or legislative requests.

3. In developing the detailed criteria, the Task Force would utilize to the maximum extent possible the information contained within the BRH publication entitled "A Study of Selected Aspects of State Control of Radiation Hazards."

4. The Task Force would not to develop criteria for nonionizing radiation sources in that adequate control seems to exist at the Federal level via the development and enforcement of performance standards. This decision will be restudied if so directed by the Conference.

RECOMMENDATIONS

1. The criteria should be distributed to each State Program Director and appropriate Federal agencies for evaluation and comment. Comments should be centrally received, collated, and the criteria appropriately revised.

2. The revised criteria should be presented to the Conference at its next annual meeting for acceptance and endorsement.

3. The Task Force is willing to act as the clearinghouse for receiving comments and revising the criteria. In this regard, funds should be alloted for one Task Force meeting to assemble the final criteria.

ADDENDUM

HEALING ARTS X-RAY CONTROL PROGRAM CRITERIA

I. Legislative and Regulations

A. The State should have enabling legislative and regulations essentially in conformity with the Council of State Governments' suggested legislation and regulations, including authority to enter into interstate and Federal-State arrangements for the control of radiation hazards. Legislation and/or regulations should contain provisions for reciprocity with other States and coverage of x radiation used in the healing arts.

B. At least every 5 years, regulations should be critically reviewed and updated as necessary. The appropriate healing arts groups should be provided an opportunity to review and comment on proposed changes.

II. Personnel

A. State radiation control x-ray program personnel should be qualified by training and experience in the field of x-ray hazards and control. Inspection personnel should include qualified college graduates and/or technicians having completed a minimum of a 2-year formal technology program in radiation control, or the equivalent.

B. Personnel for the x-ray control program should number at least 3 full-time equivalents/1000 tubes. (See appendix 1 for documentation).

C. The State should have specifications for professional employees functioning in the x-ray control field.

D. Each State professional employee should have an accurate, up-to-date description of his position, detailing specific responsibilities and authority.

E. It should be possible for any professional entering the system to progress through the various levels up to and including radiation control director.

F. Over a 3-year period, there should not be greater than a 50 percent turnover in personnel inspecting x-ray machines, except for promotions or transfers within the radiation control program. (A high turnover rate is generally indicative of problems).

III. Training

A. On-the-Job Training

A specific program should be established for on-the-job training of new employees by supervisory and senior personnel. New employees should be provided with the State regulations and written registration, inspection, and compliance programs for review.

B. In-Service Training

The State radiation control program should have a planned continuing program of in-service training consisting of seminars, demonstrations, lectures by consultants, short- and long-term training, attendance at professional meetings (Health Physics

Society, and so forth), to keep personnel abreast of current developments in the control of radiation hazards.

IV. Records

A. The State should have a records and statistical system that includes the following components:

1. a continuing integrated registration program,
2. physical survey forms containing minimum uniform data and compliance and enforcement actions,
3. data accurately and rapidly retrievable,
4. radiation control employee personnel monitoring results,
5. fiscal and other administrative records,
6. records of machine transfers and vendor notification, and
7. records of incidents and investigations.

B. The State should utilize the above records in

1. program planning and evaluation, and
2. carrying out field survey and inspection programs.

C. The State should make maximum use of available electronic data processing facilities. (See appendix II for a description of a suitable recordkeeping system).

V. Program Organization

A. Ideally all State radiation control activities should be located in the same agency.

B. Radiation Advisory Committees

The program should have a radiation advisory committee that is established to provide, as a part of its function, guidance and assistance on nonroutine, medical applications and to advise on the use of x radiation in the healing arts.

VI. Program Planning and Evaluation

Each State should have a written plan of action describing present and future program activities. The plan should include the following basic components:

1. Problem

   In defining the problem the State should include the extent, nature of the radiation exposures involved and, insofar as possible, the population affected.

2. Objectives

The State plan should set forth both long- and short-term objectives. Based on current and anticipated resources, target dates should be established for priority projects.

3. Methodology

The State plan should describe those activities directed to fulfill stated objectives.

4. Evaluation

The plan should include a method of evaluating (involving the establishment of criteria) the progress of the State programs. Important components of the State evaluation program should include an assessment of the radiation hazards and population affected for setting priorities.

VII. Public Information and Education

A. The State should maintain liaison with professional groups leading to seminars, training courses, and public documents or radiation control.

B. The State should provide x-ray registrants with current reference material, guidelines, and standards as they are available.

C. The State x-ray control program should seek opportunities to inform the public of program activities (i.e., through newspaper articles, TV, radio, incidents, and so forth).

VIII. Special Studies

State Radiation control programs should have sufficient personnel, fiscal support, appropriate instrumentation, and initiative to undertake special studies including x-ray protection; e.g., identify new problems that need investigation, develop more efficient procedures and methodology, and cooperate with Conference and/or Federal programs.

IX. Equipment

Field x-ray equipment and instrumentation should be capable of detecting and measuring x-radiation exposure to determine compliance with applicable guides and regulations and to provide estimates of radiation doses to patients, operating personnel, and the general public.

The State x-ray control program should be capable of providing and servicing of all x-ray equipment and instrumentation.

1. Ideally, a survey kit should be provided for each FTE in the field. (Refer to the Optimum Survey Procedures Manual for a partial listing of the equipment, materials, and supplies that can be useful to the field inspector. However, special equipment may be needed for special studies. For example, low-energy detectors will be necessary for evaluating mammography equipment and high-energy detectors will be necessary for certain therapy equipment).

2. There should be a system for calibration and servicing of each radiation detection instrument on a planned schedule. The schedule should call for an annual calibration

with calibration checks performed on a quarterly basis. Calibrations may be done by the State radiation control program using its own calibration source, equipment, and procedures, or by a commercial instrument calibration and repair service under contract. Such calibration and servicing should be the responsibility of one member of the program staff. Each instrument should bear a tag stating the latest date of servicing and calibration, and a calibration curve or correction factors for each detection range.

X. Registration, Inspection, and Enforcement

A. The State should have authority to register x-ray sources. Part B of the Council of State Governments Suggested State Regulations for radiation control may be used as a guide in developing the extent of the registration function.

B. Inspection

A State should conduct its own inspections, obtain survey reports from qualified private consultants or from radiation safety officers employed by the owner of an x-ray installation, or a combination of these approaches.

The qualifications for private consultants or radiation safety officers should be established when the survey reports by such individuals are used by the State to evaluate continuing compliance with its standards or recommendations.

1. Inspection Procedures

The State should have written inspection procedures to insure that uniform inspections are conducted and these procedures should be available as a guide to the inspector while in the field. The Optimum Survey Procedures Manual can be used as a reference to develop these written procedures.

2. Inspection Schedule

A periodic inspection schedule should be established. An example of such a schedule is as follows.

a. Dental x-ray machines - every 5
b. Medical x-ray machines - every 2 years
c. Hospital or similar facility - every year
d. Clinic (radiologist) - every year
e. Chiropractors - every year
f. Osteopaths - every 2 years
g. Veterinarians - every 2 years

C. The State should establish written enforcement procedures. Such procedures should detail the steps to be taken within a specified time period to accomplish compliance with the regulations (See appendix 2). In addition, interpretations based on policy decisions should be accumulated and maintained to ensure consistent enforcement policy.

XI. User Education

A. A uniform, minimum level of training in radiological health for all operators of x-radiation machines should be established.

B. The State should encourage, sponsor, or conduct continuing, formal education programs for users or operators of x-ray sources.

C. The inspector should take advantage of his time in x-ray facilities to educate, assist, and answer questions regarding radiation safety and good radiological practices.

XII. Quality Assurance

The State should have a plan to encourage and assist registrants in establishing quality assurance programs to ensure that all images are of a consistent high diagnostic quality and that all treatments are properly administered.

APPENDIX 1

The necessary fiscal support for the program described above can be computed as follows:

$$\text{Number of FTE's} = \frac{\text{Number of tubes}}{1000} \times 3$$

(professional budget) = (number of FTE's) (average cost per FTE)

Total budget = (professional budget) + (adequate clerical support)
+ (equipment)

Activities and Time Required per 1000 Tubes

Activity	Time (FTE's)
Registration	0.4
Inspections	1.0
Compliance followup	0.1
Education and Quality Assurance	1.0
Special projects	0.1
Training for staff	0.1
Miscellaneous	0.3
Total	3.0 FTE's/1000 tubes

APPENDIX 2

AN X-RAY PROGRAM RECORDKEEPING SYSTEM

A. **Registration:**

1. On receipt of an application (See Attachment 1):

   a. Check to assure that applicant has not previously been registered. The installation and not the specific x-ray unit is registered.

   b. If not registered, obtain new registration number, county-discipline-sequential.

   c. Complete registration certificate (See Attachment 2) with three carbons and send original to applicant.

2. Initiate Folder:

   a. Place application form and first carbon copy of the registration certificate in the folder. Add any other correspondence concerning this registration. File by sequence number.

3. Place second carbon copy of the registration certificate in the sequential file.

4. File the third copy in the current county file to be surveyed.

5. Two index cards (4x6) will be completed. On these cards will be the name and address of the registrant and the registration numbers. File by alphabetical discipline order and county.

B. **Change in Registration:**

1. State address change:

   a. Whenever a registrant moves from one county to another, a new certificate will be issued. Follow registration procedure.

   b. Whenever a registrant moves to a new location within the same county, no new certificate will be issued. Only change address on the present certificate, and flag for resurvey.

2. Out-of-State address change:

   a. Whenever a registrant moves out-of-State, the registration certificate will be flagged inactive and will indicate the move. The alphabetical discipline and county index cards will so indicate and be moved to the inactive status. The registration numbers will not be reissued.

3. Deaths or Retirements:

   a. Whenever a registrant dies, or retires, the registration certificate will be flagged inactive and will indicate the death or retirement. The alphabetical discipline and county index cards will so indicate and be moved to the inactive status. The registration numbers will not be reissued.

   b. After a six (6) month period, a phone call to the retiree or widow will be made to determine status of the machine. Record information accordingly.

C. Survey Forms and Results Sheets:

1. After an inspection, Survey report forms (See Attachments 3,4,5,6, and 7) will be completed, data processed, and filed in the sequence folder.

2. Also, after an inspection, survey result forms (see Attachments 8,9, and 10) with one carbon copy will be completed. The original will be left with the registrant, and the carbon is returned to the office for filing in the sequence folder.

3. No further action will be taken on facilities in compliance with the regulations.

D. Noncompliance Survey Reports:

1. As noted on bottom of survey results form, the applicant has sixty (60) days to correct items of noncompliance.

2. After an inspector returns to the office, he/she will complete a 3x5 white card with registration number, survey date, and remarks.

3. This card will be filed in the noncompliance post card file (placed behind month) 60 days from end of month in which inspection was made.

4. If the facility becomes "in compliance" before 60-day period has passed, destroy the 3x5 card.

5. At the end of each month, pull all 3x5 cards for that month.

6. Send post cards (See Attachment 11) to all appropriate noncompliances. Post 3x5 cards forward one additional month.

7. Returned post cards will be placed in sequence folder and 3x5 cards destroyed if in compliance.

8. If answer is not received in 1 month (30 days), a letter will be sent indicating inspection date, inspector, items of noncompliance, and that the applicant has 15 days to report corrective action taken.

9. If action is not reported within 15 days, a letter for the Health Officer's signature will be prepared.

10. If applicant does not respond, the case is then turned over to the Attorney General's office for handling.

E. When "Noncompliance" Items Have Been Corrected:

1. Indications from any responsible person that items of noncompliance have been corrected will be accepted. For example:

   a. Phone calls from applicant or applicant's office.

   b. Returned post card.

   c. Call or letter from x-ray representative.

   d. Letter from applicant, and so forth.

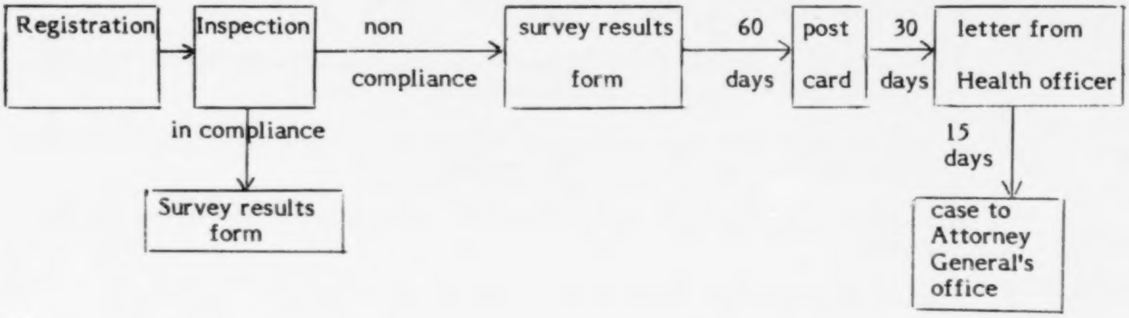
2. Upon receiving information the following will be done:

a. Survey report form will be marked compliance by indicating date information was received and by what route.

b. Survey result form will be marked compliance by indicating date information was received and by what route.

c. Three-by-five card will be destroyed.

F. A simple flow chart of this sytem follows:


Registration
Inspection
non compliance
survey results form
60 days
post card
30 days
letter from Health officer
in compliance
Survey results form
15 days
case to Attorney General's office

TASK FORCE NO. 4

NATIONWIDE EVALUATION OF X-RAY TRENDS

Beattie L. DeBord, Chairman - West Virginia

The NEXT Task Force met on January 13 and 14, 1977, in Rockville, Maryland. Those members in attendance were: Phil Babb, Kentucky, Lynn McGuire, Arkansas; Ralph Bunge, DTMA; Fred Rueter, DTMA; DeVaughn Nelson, EPA; and myself, West Virginia.

Ralph Bunge started the meeting by giving a history of the NEXT Task Force and the NEXT operations to acquaint the new members with the philosophy and development of the project. Following this, the status of several projects relating to NEXT was presented by DTMA staff members. One was the changing of the post-edit criteria in order to obtain fewer false positives.

It was reported that the incorporation of the Oak Ridge Dose Model should be completed by March 1, 1977, and dose calculations for gonads, bone marrow, and thyroid started at that time. A brief explanation of the manner of adaptation of the Oak Ridge Model was made and accepted by the Task Force.

A presentation was given on the status of the automatic exposure control project, which will produce methodology for doing NEXT surveys on x-ray machines with automatic exposure controls. One major problem is the development of a suitable phantom. DTMA is currently evaluating several concepts for a phantom. Winchester Engineering and Analytical Center has been given the task of evaluating a Plexiglas-aluminum-water (PAW) phantom that has shown promise, and this phase should be complete in June or July.

The Task Force recommended that DTMA continue its efforts in the development of a suitable phantom and a protocol for radiographic automatic exposure control (RAEC) surveys. The Task Force also recommended that DTMA try to obtain information from Kentucky, North Carolina, and Illinois on the percent of machines used in the RAEC mode.

The status of the combined NEXT/Compliance survey procedure form and manuals was presented by Fred Rueter. The forms are still at the form designer's and a computer program is being written. The associated survey manual is ready for final typing of the version that will go to the contract States.

A previous Task Force recommended that NEXT surveys be conducted in a State not having a radiological health program. This has been done and a contract has been signed with the State of Iowa to do NEXT and Image Receptor Module surveys on a sample of machines within that State. The surveys have begun.

A presentation was given on the status of a computerized tomography survey procedure. Again, the major problem is the development of an adequate phantom.

Ralph Bunge gave a brief history of the "add-on" concept to the basic NEXT survey. This concept had been developed by previous NEXT Task Forces and in essence, states that the basic NEXT survey and data should remain unchanged, but that additional problems and/or projects could be handled by additional survey protocol and data forms attached to the basic survey. The Image Receptor Module project is the first of these "add-on" studies. By the end of the pilot test, 1,400 survey forms are expected to be completed. Of the cases presently on file, the one major revelation is that there seems to be no correlation between ESE and film-screen combination, as expressed by relative speed.

The comparison of NEXT and DENT was discussed. There appears to be some discrepancy in the results from these two programs. The suggestion was made that a test be conducted in which DENT exposures would be made by NEXT surveyors at the time of a NEXT dental survey. DTMA has worked out a protocol for the study and Kentucky and West Virginia will conduct the test.

Considerable discussion ensued over instrument calibration. Gene Sullinger, DTMA, presented a plan to implement annual calibration whereby a group of States would be given a 2-month period for instrument calibration each year. During this period, States would send in whatever instruments they could spare for calibration and DTMA would give them priority treatment for a rapid turnaround. During the other periods of the year, they could send instruments, but they would not be given priority treatment. The question was raised as to whether DTMA would accept manufacturer's calibrations. DEP responded that they do not recommend accepting manufaturer's calibrations.

The NEXT exposure calculators have been mailed. If you have any questions about the calculator or would like to receive more, please see Ralph Bunge or me later.

The scope of the NEXT Task Force is:

1. To identify optimum components of a survey;
2. to provide for uniform data control;
3. to provide a system for assigning program priorities;
4. to provide a system for measuring program effectiveness;
5. to categorize and determine the relative frequency of the source of poor radiographic quality as these exist in practce today; and
6. to develop exposure ranges which can be recommended for use by participating States in aiding facilities with maintenance of consistent high quality diagnostic radiography with minimal exposure to the patient.

It was observed by members of the Task Force that items 1 through 4 had been addressed by previous Task Forces and resulted in the Optimum Survey Procedures Manual and the Organ Dose Index System. Item 5 was perceived as a charge that would better fit into the newly-formed Quality Assurance Task Force, but the NEXT Task Force will assist in any way possible. At present, the NEXT system does not evaluate film quality, and therefore cannot categorize the source of poor radiographic quality.

A first look at item 6, that is, the development of exposure ranges, would be a careful examination of all projections above the 75th percentile in ESE's. Considerable discussion ensued; one major point was that perhaps we should also look at the low exposures and try to determine if usable radiographs are being obtained. It was recommended that any exposure range developed be reviewed by radiologists and other professional groups. Such endorsement by professional groups is essential for the effective use of any sort of exposure recommendations.

The Task Force recommended that DTMA develop a short handout or brochure explaining the NEXT program to physicians and dentists for presentation to them upon completion of a survey at their facility. The handout could contain the first and third quartile and the mean ESE's for each projection, with a blank space left for the field surveyors to write in the estimated ESE when the survey is complete.

Under old business, the question of whether NEXT should collect data on gonad shielding was discussed. A previous Task Force had recommended against this, as does this Task Force.

Also under old business, the effect of half-value layer and energy dependence of instrumentation on exposure was discussed. Fred Rueter stated that DEP is looking into this problem.

TASK FORCE NO. 5

CREDENTIALING OF RADIATION ALLIED HEALTH OPERATORS

Donald R. Hughes, Chairman - Kentucky
Joseph Capella - Florida
Wayne Carlson - Minnesota
Howard Goldman - New York
Dennis Hahn - Michigan
Ray McCandless - Vermont
Ellis Simmons - Nebraska

Robert Eccleston - BRH

INTRODUCTION

Recognizing the need for operators of sources of ionizing radiation in the allied health professions to be uniformly proficient in the performance of their duties, the National Conference of Radiation Control Program Directors, based on a recommendation of Workshop No. 8 (Springfield, 1976), established a Task Force to study the needs of a credentialing program.

The purpose of this Task Force (No. 5) was to develop recommendations on the design of a credentialing system for radiation operators. The objective of Task Force No. 5 was to include the development of a conceptual framework for a credentialing system, including but not limited to:

1. Determine purposes, goals and relationships in a credentialing system and define its options.
2. Evaluate the advantages and problems related to existing and proposed credentialing activities.
3. Identify the occupational groups that should be included in the credentialing system.
4. Propose a framework for a credentialing system including but not limited to proposals for structure, functions, and financing.

This Task Force was active throughout the year gathering information from the Bureau of Radiological Health, numerous states, resource persons, and professional organizations. This information, in the form of questions and answers relevant to credentialing, was primarily utilized as a basis for the development of this report.

RESPONSE OF THE TASK FORCE TO PROPOSED OBJECTIVES

This Task Force recognized that the objectives as proposed by Workshop No. 8 were, in some instances, broad in scope; therefore, we were not always able to direct our responses to the entire range of the objectives.

OBJECTIVE: **Determine purpose, goals, and relationships in a credentialing system and define its options.**

RESPONSE: The purpose of credentialing is to provide a mechanism for protection of the public by reduction of nonproductive ionizing radiation exposure in the healing arts.

The Task Force determined that credentialing shall be mandatory and should be in the form of licensing, certification, or registration, depending upon local government definitions. This is further qualified by the following statement: "It shall be unlawful for a noncredentialed individual to intentionally expose any person to ionizing radiation."

It was the unanimous conclusion of the Task Force that MINIMUM NATIONAL STANDARDS should be established for the credentialing of individuals and that credentialing programs shall be State administered and controlled.

OBJECTIVE: **Evaluate the advantages and problems related to existing and proposed credentialing activities.**

RESPONSE: One of the chief advantages of a comprehensive, mandatory credentialing system, is that it will provide a tool to achieve 100 percent coverage of the allied health radiation work force. The Task Force believes that this coverage can achieve the following results:

a. Provide and maintain a uniform level of competency for those operators who are not now voluntarily credentialed.

b. Upgrade and maintain a uniform level of competency for those who are presently voluntarily credentialed.

Available evidence has shown that credentialing, in some form, has resulted in improved job performance and reduced patient exposure. This Task Force recognized that credentialing, by itself, will not solve the entire problem of reduction of nonproductive ionizing radiation exposure to the patient.

In order to achieve the purpose of credentialing (i.e., reduction of dose to patients) such things as training levels, individual skills, and a comprehensive evaluation program need to be considered. The problem, as it exists today, is how does one credentialing system provide a mechanism for all States to guarantee that all allied health radiation operators are at least equally competent at some level? Minimum credentialing standards would assure that this competency level is achieved and maintained.

OBJECTIVE: **Identify the occupational groups which should be included in the credentialing system.**

RESPONSE: The following occupational groups have been identified and are presented in order of their priority for credentialing:

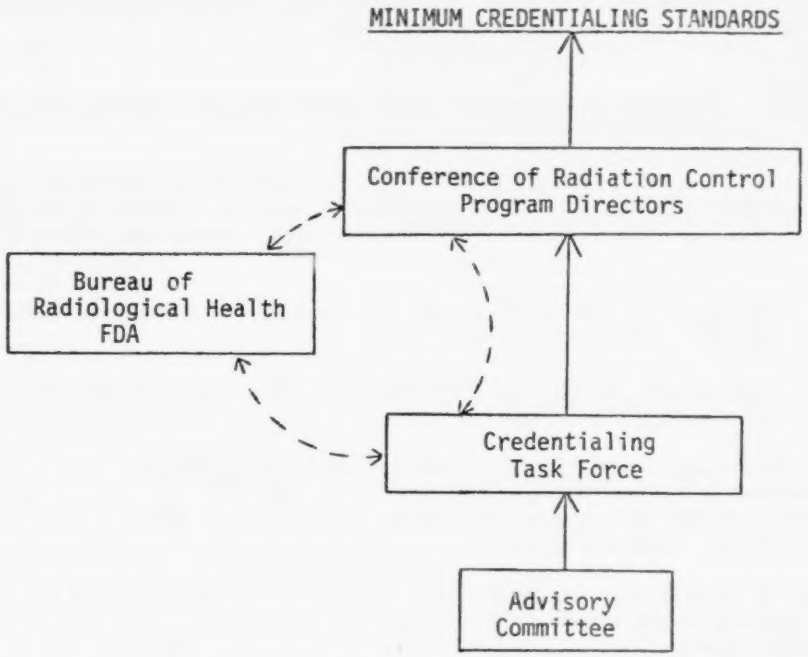
a. Diagnostic Radiologic Technologists/radiation operators.
b. Nuclear Medicine Technologists/technicians.
c. Radiation Therapy Technologists/technicians.

In addition to those groups mentioned above, the Task Force did recognize the existence of other occupational groups utilizing ionizing radiation; however, groups such as these (industry, industrial radiographers, academic, and so forth) are not part of the allied health work force and were therefore not considered at this time.

OBJECTIVE: **Propose a framework for a credentialing system including, but not limited to proposals for structure, functions, and financing.**

RESPONSE: It was concluded that the Conference should be the primary organization involved with the development and implementation of any credentialing system. As previously stated, credentialing programs shall be State administered and controlled; therefore, the Conference, because of its structure, would be the natural promulgating body.

The following outline was proposed as a structural framework for development of such a program:


MINIMUM CREDENTIALING STANDARDS
Conference of Radiation Control Program Directors
Bureau of Radiological Health FDA
Credentialing Task Force
Advisory Committee

Assuming the Conference does proceed with the concept as outlined above, it shall be necessary to appoint an ongoing Task Force to develop credentialing mechanisms.

FUNCTIONS OF AN ONGOING TASK FORCE

The major functions of the credentialing Task Force would be as follows:

a. Recommend to the Conference, for approval, Minimum Credentialing Standards and Implementation Guidelines and make available all necessary information to support these recommendations.

b. Develop the composition of an advisory committee, when necessary, to assist in the formulation of Minimum Credentialing Standards and Implementation Guidelines. This requires the following:

   1. Identify charges to an advisory committee and provide ongoing direction;

   2. Participate in advisory committee activities;

3. Coordinate outside group review (i.e., States, interested and affected professional groups, and so forth).

c. Assist States in the development of credentialing programs.

d. Obtain data from States to assist in the evaluation of credentialing programs with special emphasis on patient dose reduction.

PROPOSED ORGANIZATIONAL STRUCTURE AND FUNCTION OF AN ADVISORY COMMITTEE

The Credentialing Task Force recommends that an advisory committee to this body be appointed by the Conference to develop Minimum Standards for credentialing of allied health personnel.

This committee shall be composed of at least ten (10) members. It shall have at least one representative from the following groups, organizations, and/or associations:

1. Bureau of Radiological Health (BRH)
2. American College of Radiology (ACR)
3. American Registry of Radiologic Technologists (ARRT)
4. American Society of Radiologic Technologists (ASRT)
5. American Registry of Clinical Radiography Technologists (ARCRT)
6. Joint Review Committee on Education in Radiologic Technology (JRCERT)
7. Health Physics Society (HPS)
8. A member of the general public
9. A recognized testing and evaluation group or individual

(In addition, the Conference shall appoint such persons as it deems necessary to balance or add to the Committee's expertise.)

It is the opinion of the Task Force that an advisory committee is essential in developing the basic mechanisms for a credentialing system. The composition of the proposed advisory committee is set up in such a manner as to allow affected segments to be represented. Because of the vast amount of material to be filtered and selected by the Task Force and because of the need for a reasonable, well thought out set of minimum standards for credentialing, a select advisory committee is essential.

THE TASK FORCE APPROACH TO THE DEVELOPMENT OF A PROPOSED SET OF MINIMUM STANDARDS FOR CREDENTIALING

Assuming the Conference does establish a task force to develop Minimum Standards for credentialing allied health personnel utilizing ionizing radiation, then an organized approach to development of such standards must be made.

It is the recommendation of this Task Force that criteria, techniques, and outlines be established to delineate the following essential components in order to derive Minimum Standards. The basic components are:

1. Definitions
2. Basic entry requirements
3. Types of credentials (e.g., general; limited; special; temporary; hardship)
4. Exemptions
5. Renewal requirements
6. Enforcement mechanisms
7. Performance evaluation
8. Fees

9. Administrative mechanisms
10. Reciprocity
11. Testing and/or evaluation procedures
12. Ethical code of conduct
13. School accreditation
14. Challenge procedures
15. Continuing education

(The above mentioned components may not be all inclusive and other areas may need to be considered.)

Appendix A contains a series of questions and answers generated by the Task Force, relevant to the components presented above. The questions and answers are indexed in this appendix according to the above component which they address.

The Task Force has obtained numerous questions and answers relative to the total credentialing program. Because of the large volume of information we were not able to incorporate all of the material into this report but the Task Force will make this information available upon request.

The Task Force recognized that many of the above mentioned components were addressed in earlier attempts to produce credentialing standards by the Bureau. Those published documents may well serve as a basis to begin the development of standards to be accepted by the Conference.

Once the Conference adopts and promotes a set of minimum standards, it can then assist the States in the implementation of those standards into a credentialing system.

SUMMARY AND CONCLUSION

This Task Force concluded that:

1. **A credentialing system shall be mandatory.** A mandatory system is necessary for the protection of the public by reduction of nonproductive ionizing radiation exposure. By mandatory, the Task Force implies that at some time within a fixed period all States shall adopt a credentialing program. Currently those States possessing a credentialing program have developed such a program in an independent manner. A degree of uniformity needs to be added so that certain concepts such as reciprocity, grandfathering, and so forth, can be accepted throughout the States.

2. **It should be controlled and administered by the States.** In order to provide a credentialing system with the necessary flexibility, the Task Force recommends that the programs be State administered and controlled. This administration by the States and local governments would allow a degree of flexibility not always available in a Federally developed program.

3. **The Conference should be the promulgating body responsible for the development and approval of the credentialing system.** In order to establish a set of minimum standards there needs to be an officiating body. The Task Force feels that the Conference, because of its unique position, can provide the necessary guidance to develop standards. Once those standards are developed, the Conference can offer its support to the States to assist them in their implementation of those standards.

The Task Force felt that the resistance to the development of Federal Minimum Standards was to be expected because of the removal of State involvement and the need for input from those groups directly affected. Because of this, we felt that the Conference could be very successful in developing standards and getting those standards accepted using the approach described herein.

4. **Minimum standards should be established for all States to use.** In order to achieve uniformity throughout the States and provide a mechanism for the development of a credentialing system, the first step would be to develop a set of Minimum Credentialing Standards. Those standards, developed by individuals and groups being regulated and those regulating, would have a far greater acceptability and would be more likely to achieve the ultimate purpose of credentialing; which is, dose reduction to the public.

5. **An ongoing task force should be charged with the responsibility of coordinating all data and make recommendations to the Conference on Minimum Credentialing Standards.** The Conference can best develop a credentialing mechanism by convening an ongoing task force to assist in the development of a credentialing program. This task force can organize, coordinate, and recommend to the Conference those essential items necessary to be included in a credentialing system.

6. **An advisory committee to the ongoing task force should be convened to aid the task force in developing standards.** This Task Force recognized that the potential of any task force to develop these minimum standards would indeed be difficult. Therefore, this Task Force recommended that an advisory committee be established to aid in the development of standards. The proposed makeup of this advisory committee is of significant importance to the end result. We feel that the advisory committee should be composed of those special interest groups, State, Federal, and otherwise interested organizations that would be ultimately affected by the development of a credentialing program. In this manner, standards established by an advisory committee through a task force, ultimately to the Conference for approval, would be of significantly more meaning than those established by any other independent group. For this reason the Task Force is strongly in favor of the utilization of an advisory committee to assure that any standards recommended to the Conference are workable and meaningful to all those regulating or regulated.

7. **Guidelines should be established to aid in the implementation of these minimum credentialing standards.** Once a system of credentialing has been established with all of the necessary criteria, the Conference should then establish guidelines to assist States in implementation of the credentialing system.

APPENDIX A

1. Definitions. No definitions were developed by this Task Force because definitions will be based on future Minimum Credentialing Standards.

2. Basic Entry Requirements

Question: If grandfathering is incorporated into a credentialing program, should it be restricted in any way, such as, "only those currently employed," passage of an examination, employed for a specified period of time, and so forth?

Answer: "Conditional Grandfathering" shall be incorporated into a credentialing program and should be directed toward proof of basic competence by an examination within a fixed period of time.

Question: Should examination requirements be waived for ARRT certificate holders?

Answer: Examination requirements will not be waived, but will be evaluated for all voluntary professional credentialing organizations.

Question: Should the "general credential" be based upon the 2-year school exclusively (once "grandfathers" are processed)?

Answer: The task force does not agree that a 2-year exclusive criteria is the optimum basis for credentialing.

3. Types of Credentials

Question: Should there be different categories (general, limilted, and so forth) for credentialing radiation operators?

Answer: Yes.

Question: Assuming a mandatory credentialing system, other than for students attending approved schools, should any exception to the licensure requirement be provided, such as, "hardship basis," geographic areas, certain classes of practice, and so forth?

Answer: Yes, exceptions should be allowed and should be handled on an individual case by case basis.

Question: To what extent can or should uniformity be established among States (and with ARRT) in classes of credentials issued, requirements of training or experience, and so forth?

Answer: Uniformity should be established among States in classes of credentialing. By adopting uniform minimum standards, States would at least achieve some degree of compatability that would aid in the development of educational requirements and possible reciprocity.

4. Exemptions (types or kinds of exemptions were not discussed by this Task Force).

5. Renewal Requirements

Question: Should continuing education be incorporated into a credentialing program for license/certificate renewal?

Answer: Some form of continuing evaluation and/or education of the credentialed individual shall be mandatory based on local government designs.

6. Enforcement Mechanisms

Question: Can Federal funds be withheld from physicians, clinics, and hospitals that do not establish certain performance standards of its operators?

Answer: Yes.

Question: Does Medicare/Medicaid funded services require credentialing of its x-ray operators?

Answer: This is a requirement, but it does not specifically address credentialing.

7. Performance Evaluation

Question: What type of examinations would be the most appropriate and feasible: written, multiple-choice, essay, practical, oral, or any combination thereof?

Answer: The Task Force recognizes that a uniform test must be adopted on a national basis to evaluate the proficiencies of the potential credentialed individual. We recommend that input be solicited from the Conference on any testing mechanism.

8. Fees

Question: Should a credentialing program be supported by fees, general revenue, or a combination of both?

Answer: Funding for such programs should be based on local government directives; however, it is felt that a "combination" would be the most practical approach.

9. Administrative Mechanisms

Question: If there is to be credentialing, should the program be administered by the State, Federal, or a combination of the two?

Answer: State administered using Federal minimum standards.

Question: Relative to the accreditation of schools, is it preferable for the States to:
a. Directly accredit schools themselves?
b. Work in cooperation with the Joint Review Committee (JRC)?
c. Rely completely on the JRC to accredit schools?

Answer: Local governments shall have the control over the mechanism for accreditation of their training programs. Where possible, we recommend that States work closely with the JRC or other accrediting bodies.

10. Reciprocity

Question: Can there be some degree of reciprocity between States when discrepancies exist in classes of credentials issued, qualifications required, nature and difficulty of examinations, and so forth?

Answer: Complete reciprocity between States will be difficult; however, we feel that negotiations should be conducted between individual States.

11. Testing and/or Evaluation Procedures (See question and answer to 7. Performance Evaluation.)

12. Ethical Code of Conduct

Question: Should standards of "moral character" be established for denials or revocation of credentials?

Answer: Standards for an ethical code of conduct shall be established for revocation, suspension, or denial of credentialing for any individual who engages or has engaged in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public.

13. School Accreditation

School accreditation will largely depend upon the administrative mechanisms established by each State; therefore, please refer to the questions and answers to 9. Administrative Mechanisms.

14. Challenge Procedures

Challenge procedures are obviously related to "Basic Entry Requirements" and "Types of Credentials;" however, this type of mechanism should be thoroughly researched with each State's Department of Education prior to making it a part of a State's regulations.

15. Continuing Education

Question: Should "some amount" of continuing education be a mandatory prerequisite for license or certificate renewal?

Answer: Yes. Continuing evaluation, whether in the form of continuing education or proficiency examinations, must be incorporated into all State credentialing standards.

TASK FORCE NO. 6

SUGGESTED STATE REGULATIONS

Charles P. Froom, Coordinator
Bureau of Radiological Health, FDA

As many of you are aware, the Suggested State Regulations are actually a cooperative project of the Conference and a number of Federal agencies. In the 1974 revision, it was the Conference, the Bureau of Radiological Health, and the NRC that worked together on this project. In this last revision, which we are about to complete, the EPA has joined as one of the sponsors. I should mention, too, that OSHA and NIOSH and other Federal agencies are invited to participate in the meetings and have an opportunity to review drafts that are prepared. We are hoping, by expansion of agency involvement that it will aid in providing consistency among regulations in the area of radiation control.

As to staffing the working groups for the various parts of the model regulations, the Conference assigns 1 to 3 individuals to work on each part. The number of individuals assigned is dependent upon the amount of work involved and whether a complete revision of that part is plannned or only an incorporation of certain comments. The Federal agencies assign individuals to each part, depending upon their particular interest or responsibility in that area; for example, on the basis of their regulatory authority in that particular area. The chairman of each part is a Conference representative. We have learned that it is extremely important to keep the same members on the working group throughout the revision in order to complete the task and not to waste time or to orient new people at a later stage of development. Throughout this discussion I will be referring to certain members of the working group, but I would like to point out that these are the people who were involved in the current revision. Some new members have been assigned for the next revision as well, but I will be speaking of this current revision that we are now completing. Also, the Executive Committee of the Conference has designated two persons to serve as liaison between the working groups and the Executive committee. Alice Dolezal is responsible for the medically oriented parts, and Jim Porter is responsible for the environmental parts. This has been a big help to us. As we add more parts to the Suggested State Regulations, the coordination of all the parts becomes more difficult. We greatly appreciate the assistance that these two individuals have provided to us.

After completion of the last revision of the Suggested State Regulation in 1974, we published a Notice of Availability in the FEDERAL REGISTER with the intent of making it available to others in need of this information. We hoped that it would help to promote uniformity among voluntary and regulatory standards. We also wanted to invite comments from interested persons and groups on these model regulations. Before it was published, we had the notice reviewed and concurred in by the Conference, the Bureau, and the Nuclear Regulatory Commission. We also provided copies to EPA and OSHA for their review and concurrence. Based upon this notice, comments were received on all parts of the model regulations. In some cases, these comments were fairly minimal on certain parts, and in other cases fairly extensive comments were received. The comments upon receipt, are provided to the working groups of the appropriate parts for their consideration and action.

In addition to the revisions that were completed based on these overall comments, some parts have also received major revision. In some cases, the chairman of these working groups sent out a notice of intent to revise a certain section or part requesting the States to send in any comments, suggestions, or ideas that they might have for revision.

We have also developed a special mailing list for sending drafts out for review. This includes all of the State radiation control programs, Federal agencies with an interest in radiation control, professional organizations, standard setting groups, and industrial associations. There are approximately 220 on the list at this time. By doing this, we hope to provide an adequate opportunity for review during the draft stages of the various parts of the model regulations.

At the outset of work on this revision, we also prepared guidelines which were sent out to all of the working group members to assist them in understanding the procedures involved in review and revision of the regulations. We included target dates for completion of final drafts, and the working groups were requested to provide plans reflecting the steps that they would take for completion of their part. We also set forth criteria and methods for revision.

We have found it very important in working on these model regulations to prepare a rationale and analysis of comments document along with development of the part. The rationale document, of course, explains the reasons and thinking of the working group on certain provisions as well as any references or resources that they have used in the development. From reports that we have received from the States when they are revising their own regulations, the rationale has been very helpful in justifying their regulations to advisory groups or any other oversight groups within the State. Development of the analysis of comments document is needed to provide a means for organizing the comments, for analysis, and for action by the working group. It also provides a record of the analysis and action upon the comments submitted by State personnel and others. In reviewing each of the comments, you have to analyze and decide how you are going to handle these; it is then a matter of documenting this on paper. Upon request, we want to be able to provide to State people and others who submit comments specific information on the analyses and actions taken on their comments. This document serves to provide that information.

It is a tremendous job organizing the comments and preparing the analysis and action taken on each comment. Just to give you an idea, 384 comments were received on Part F, including 175 comments on Section F.9 on therapy. I say this to remind you to please be patient if you want to know early as to how your comment was handled. The working group may not have it initially, but in time we hope they will have all of these comments analyzed and ready in an analysis of comments document that would be available to you upon request.

One other method that we have used in this last revision is conference calls. In an attempt to cut down on travel, we have arranged for some working groups to discuss their part on a common telephone circuit, in one case for about 2 hours every week or two over a period of several months. This method was used in discussing and analyzing comments. We did find that it is not nearly as effective as getting together personally, and it is not really inexpensive either. It would be adequate, however, for very minor changes on a part.

For the next revision, we are considering a preliminary planning meeting for the working groups. The idea would be to review the procedures that are used, especially for new members of working groups, and to discuss any additional sections or parts that might be included in the next revision. It would give the working group chairman an opportunity to set out his plans for revision and coordinate this with other working group chairmen. We are not sure at this point if we will be able to do this; travel is restricted through the rest of this calendar year, but it is something that we are considering at this time.

The present plan for revision of the model regulations is that it will be done on a continuing basis. When this present revision was started, we thought that it might be possible to complete a new edition annually. We found that the workload is too great to do this, particularly for the State people participating in sections or parts requiring major revision, since this is work that must be done above and beyond regular duties and job responsibilities. After we found that it was not feasible to keep the annual schedule, we met with the Executive Committee of the Conference and it was decided that approximately every other year would be a more reasonable time to complete a new edition.

The model regulations are organized into an ionizing radiation category and a nonionizing radiation category. The ionizing radiation category has ten active parts and two other parts are under consideration. There is some interest in other areas that might be added later. In the nonionizing area, at the present time we have only the laser model regulations. We may want to consider some additional regulations in other nonionizing areas in the future.

Dale McHard will discuss the Technical Review Committee with you. I feel that the work of this committee is extremely important. Once we have completed the final draft of the model regulations, it goes out to the Executive Committee of the Conference and to all of the participating Federal agencies for their concurrence. Therefore, this provides a mechanism whereby the Technical Review Committee can make recommendations to the Executive Committee on adoption, or on what changes need to be made for the Executive Committee. It would be an overwhelming job to ask the Executive Committee to review everything themselves. Likewise, the Federal agencies have representatives available at the Technical Review Committeee meeting and have an opportunity to know exactly what the changes have been in revision of the model regulations. They, in turn, can recommend to their agency head or whoever signs concurrence for the final draft of the model regulations. That group has really done an outstanding job and has put in a lot of hours in hard work this last fall in reviewing our current revision.

I would like to mention the status of some of the parts of the model regulations. Part E, Industrial Radiation, was not revised for the 1974 edition. It was delayed to incorporate the final provision of the cabinet x-ray standard. In the early planning for work on Part E, letters were sent out to the States requesting their input and ideas on Part E. Following this, a preliminary draft and rationale was prepared, and this was sent out to all of the people on the mailing list. Since that time, Part E and the rationale have been revised based on the comments received and an analysis of comments document has been prepared. We have received some additional comments from NRC that have been analyzed and the part and rationale has been revised further. The Technical Review Committee reviewed and approved this part at their November meeting. The members of the working group are Jim Porter, Chairman; Ed Bailey, Texas; Joe Franaszek, California; John Taschner, BRH; and John McGrath, NRC.

On Part F, X Rays in the Healing Arts, the diagnostic x-ray portions were completely revised in 1974. This incorporated the provisions of the diagnostic x-ray standard. Some of the States have chosen to adopt this standard by reference. In the current revision, major efforts have been devoted to x-ray therapy in Section F.8 and F.9. At the outset of this revision, Ms. Dolezal sent a letter to all of the Conference members requesting any ideas and suggestions that you might have on revision of the therapy sections. Following this, a preliminary draft and rationale was prepared and was sent out for review to these various groups. On Section F.8, there were 64 comments received, and on F.9, 175 comments. There were also 145 comments received on the diagnostic x-ray sections of Part F, and these sections have been revised to reflect those comments as well as some amendments to the Federal diagnostic x-ray standard. The Technical Review Committee reviewed all of Part F except Section F.9, but Section F.9 has been completed by the working group. It is available at this time for the Technical Review Committee. The veterinary medicine section has been deferred until the next revision because of the heavy workload on the other sections. The members of this working group are Alice Dolezal, Chairperson; Coleman Smith from Oklahoma; and Bob England from California.

Part G, Sealed Sources in the Healing Arts: A letter was sent out on this part to all of the Conference members asking for their comments on portions needing revision. Part G was revised based on this and comments received from the Notice of Availability. It was reviewed and approved by the Technical Review Committee at their meeting last fall. A new group has been assigned to Part G, and they met in Atlanta this year in January, discussed their plans for the next revision, and intend to send out a questionnaire to all the States and Federal agencies regarding possible changes needed. The working group on the completed revision of Part G was Dale McHard (presently Jerry Morris of Georgia is the Chairman); Don Thompson from BRH, and John McGrath from NRC.

Part H, Analytical X-Ray Equipment, is one of the new parts that was added in 1974. There were some comments that came in in response to the Notice of Availability. Analysis has been done on all of these comments, proposed changes were presented to the Technical Review Committee this fall, and it has been approved by them. The working group members of this part are Bill Aaroe, Chairman; Don McDonald from Pennsylvania; and Tom Moore from BRH.

Part I, Particle Accelerators, was also another new part added in 1974. Some comments were received from the Notice of Availability on this. They have been analyzed and appropriate action prepared. The Technical Review Committee went over the analysis and action prepared by the working group and approved that at their meeting this fall. The members of this group are Tom Gerusky, Chairman, Pennsylvania; and Bob Jacobs from BRH.

Part J on "Notices, Instructions and Reports to Workers; Inspections" was the third new Part added in 1974, based on the OSHA requirements and Part 19 of Title 10. At the outset of working on this, you may recall Mr. Brunner sent out a questionnaire to all of the States asking for any ideas, comments, or suggestions that they might have on this part. It was then revised and a rationale prepared on the basis of comments that you supplied to him. This draft was sent to OSHA, to NRC, and other agencies represented on the working group for review. Some comments were received back from NRC and OSHA approved the changes that were made. This, too, was presented to the Technical Review Committee and approved last fall. Members of this group are Phil Brunner, Chairman; John McGrath from NRC; Lou Garcia from EPA; and myself.

Part C, Licensing of Radioactive Material: One of the Conference task forces recommended that bonding and perpetual care requirements be added to Section C.25. This has been done, and definitions in support of this have been added to Part A. You have already heard Al Hazle discuss the concept of the Licensing State, in regard to licensure of NARM materials. The Part C group has worked very closely with Task Force No. 1, and we are hoping that this question will be resolved here at the Conference. It will be discussed at your business meeting. The working group members of this part are Al Hazle, Chairman; Jim Blackburn, Illnois; John McGrath, NRC; and Al Tapert from the Bureau.

Part D, Standards for Protection: Most of the changes made to this part were based on amendments to NRC regulations. Currently, the members of this group are Jerry Allen, Kansas, Chairman; John McGrath, NRC; Gail Schmidt, BRH; and DeVaughn Nelson, EPA.

Part A, General Provisions: Most of the changes made to Part A were the addition of definitions in support of revisions made to other parts such as NARM, Licensing State, Bonding and Perpetual Care, and some NRC amendments that require definition. This part was reviewed by the Technical Review Committee and approved last fall. Members of this group are Gene Christianson, Chairman; John Munzer, BRH; John McGrath, NRC; and DeVaughn Nelson, EPA.

Part B on registration: This part received major revision in 1974, and a few comments were received on this since the last revision. The final draft was reviewed and approved by the Technical Review Committee last fall. Members of this group are Don Van Farowe as Chairman and Lois Miller from EDRO.

There are two new parts that have been proposed for inclusion in the model regulations. One is Part K on Nuclear Pharmacies. A preliminary meeting was held on this in Seattle, November 12-13, 1975. Earlier this year (April 25, 1977), a meeting was held in Rockville in which a proposed draft of regulations was reviewed. Also present were representatives of the American Pharmaceutical Association and the National Association of Boards of Pharmacy. I understand that the American Pharmaceutical Association met in early May and endorsed in principle the proposed regulations. The National Association of Boards of Pharmacy met later in May and also endorsed them. Lynn FitzRandolph is the Chairman of the group. Other members include Dave Lacker, Bob Will, and Ellis Simmons.

There is also a proposed Part L on nuclear medicine. Jerry Allen from Kansas is presently chairman of this group. They met in Kansas earlier this year and did some preliminary planning for the next revision.

That concludes the ionizing area. For the nonionizing area, there is only the one part, Suggested State Regulations for Lasers. This working group met in June the past year, they revised their earlier draft, and developed a rationale report. This was sent out for preliminary review to selected States who have laser legislation and regulations, and certain Federal agencies. In August, the group prepared an analysis of comments on those received and revised their draft and rationale. They met June 8-10, 1977, in Rockville to consider consistency of these proposed regulations with the Federal laser standard, and they also considered the development of guidelines on laser shows. The guidelines are to be added as an appendix to the model regulations to indicate how the regulations would apply to laser shows and lasers used in rock groups. They will be meeting this afternoon to complete their work on the draft. Following that, we will send their draft out to all of the States and other groups for review.

In summary, then, I might mention that with a project of this nature, when you consider the number of individuals and agencies and groups involved and working on a voluntary basis, you are bound to have delays. However, I am happy to say at this point that the work on Section F.9 on x-ray therapy has been completed and is ready for the Technical Review Committee. This past week we received some amendments to Title 10, with the rationale for incorporation into Parts A, C, and D. The executive Committee of the Conference in the business meeting will be discussing the Licensing State concept, and we hope that will be resolved here so we can complete the final draft. At that time we will send copies out to all of the States.

In the future, there will be some other areas considered for inclusion in the model regulations. You heard earlier the possibility of oil well logging and the task force for natural radioactivity contamination problems mentioned earlier that they had some proposed regulations for consideration. So, at this point, I would just like to thank all of the working group members for their hard work during the past year, and also would like to thank the Executive Committee and Federal agencies for their support in this area.

TASK FORCE NO. 6

SUGGESTED STATE REGULATIONS

TECHNICAL REVIEW COMMITTEE

J. Dale McHard, Chairman - Oklahoma
B. Jim Porter - Louisiana
Al J. Hazle - Colorado

This committee has been in existence for a number of years, and it has met sporadically as needed. Furthermore, the Technical Review Committee will continue to function with the same members subject to approval by the Executive Board until the 1977 edition of the SSRCR is published.

I feel that there is some confusion about this committee, perhaps because of its lack of visibility, so I will take some time to discuss what the functions and objectives of the Technical Review Committee are. In discussing the charge of the committee, I will quote from the letter of November 8, 1976, from Chairman Parker to the committee as follows:

> "The committee will serve as the final reviewers of the current revision of the SSRCR and hopefully resolve any possible conflicts within or among the parts and other supporting documents. It is also intended as a mechanism for achieving agreement among sponsoring groups of the SSRCR of the final draft and rationale for this revision."

In meeting with the Working Groups for each part of the SSRCR, prior to our meeting with those groups, and also during those meetings, we asked the chairman of the working group to provide us, the committee, with certain information as follows: A summary of the discussion by the working group on their part, including decisions reached as to changes on the draft part, the rationale, the analyses of comments; that is, those comments which they have received from outside commentators, and items to be included in matters for future consideration. Now, matters for future consideration are those which, for a variety of reasons, cannot be included in the SSRCR but are felt to be important enough to be held over and actually placed in the record for possible future consideration. I will give you two examples of those later.

Second, we asked the working group chairman to provide us with a draft of the part with the changes that the working group had decided upon. Three, we requested a draft rationale for the 1976 revision, indicating the reasoning behind those changes made from the 1974 SSRCR. Matters for future consideration were to be included in this rationale. Four, we requested a completed draft analyses of the comments (i.e., those comments from outside commentators), which are consistent with the changes made to the part and with the rationale.

At that point in meeting with the working group chairman, the Technical Review Committee proceeded to review that particular part for consistency of editorial form, numbering format, and typographical and grammatical errors. In addition, on occasion we did inquire into, and on occasion, did make changes involving content. However, the Technical Review Committee made no changes of this type unless (1) the task force chairman and/or a resource person from one or more of the Federal agencies brought up an issue that caused this change to be made, (2) a major issue was raised by one or more of the commentators, or (3) if the Technical Review Committee members recognized a matter that they believed deserved further discussion or change.

In general, our policy in regard to these changes were that the Technical Review Committee felt that the content and intent of each part was the primary responsibility of the working group responsible for that part and that the Technical Review Committee should not override this responsibility except where necessary.

Our accomplishments were that we met during the weeks of November 15 and December 19 of 1976 at BRH headquarters in Rockville, in each case for a full week. Very briefly summarized, we can advise you at this time that the committee has reviewed all parts of the SSRCR with the exception of certain sections because of circumstances outside our control. Part F, the use of x rays in the healing arts, has not been completed as yet by that working group, and, therefore, this part has not been reviewed totally by the Technical Review Committee. In addition, Part C, as written by the working group and reviewed by the Technical Review Committee contains the Licensing State concept that will be discussed further at the Conference business meeting tomorrow.

In regard to matters for future consideration, the Technical Review Committee has found a relatively large number of such items. Two worthy of mention here are the regulation of the use of sources in well logging and the stabilization of radioactive mine milling waste retention systems. Both of these matters could possibly become new parts of the SSRCR ultimately.

At this time the committee would like to acknowledge with great thanks the help of a gentleman who has been absolutely invaluable to us in our task in this review--Chuck Froom. He is the coordinator of all of the various parts of SSRCR and has taken care of a large number of details that otherwise could not have been handled very well. In addition, we found him to be a very congenial and hospitable host. We thank you very much for all your help.

We would like to also acknowledge the assistance of John McGrath of the Nuclear Regulatory Commission for his assistance to the Committee. He was most helpful because of his knowledge of the regulations of the NRC, and of the suggestions for phraseology in order to bring the SSRCR language into compatibility or agreement with NRC regulations.

There were a large number of other people who we should acknowledge, and who we do acknowledge their help and express our thanks; they include all the working group chairmen and a very large number of resource people from the various Federal agencies.

Finally, I would like to say that the task of the Technical Review Committee has been monumental. However, we members of that committee enjoyed the hard work thoroughly, the reason being that we could see, because we were very closely identified with it, the object of our endeavors and our labors; that is, a new and shining and hopefully good edition of the SSRCR. At this time I really cannot tell you, either as the chairman of that committee or as your chairman-elect, exactly when you will have a newly published edition of this SSRCR. However, the Technical Review Committee will certainly do its part to see that that publication date is in the near future.

TASK FORCE NO. 6

SUGGESTED STATE REGULATIONS

PART C - LICENSING OF RADIOACTIVE MATERIAL

A. J. Hazle, Chairman - Colorado

On January 28-30, 1976, the Part C Working Group met in Rockville, Maryland, reviewed and acted upon all comments received for Part C of the October 1974 edition of the SSRCR. Certain changes were made and rationale for the changes were discussed. These changes and the respective rationales were recorded at that time.

The terms "NARM" and "Licensing State" were accepted in concept and the Working Group Chairman requested that the BRH and NRC representatives make any necessary refinements of these terms. Three items were assigned as "Matters for Future Consideration."

In all, 2-1/2 days were spent in the total meeting effort. The first day was spent discussing philosophical aspects of materials licensing, particularly NARM. The second day entailed a thorough review of Part C and amending certain aspects of it regarding updating with NRC regulations and insertion in appropriate locations the Licensing State terminology. The last half-day encompassed gathering loose ends together and drafting a summary report.

At the annual meeting in Springfield, the Chairman did meet with the Executive Committee of the Conference; however, inadequate time was provided to address the Licensing State concept properly.

During the week of November 15-19, 1976, the Task Force met with the Conference's Technical Review Committee (TRC) in Rockville, Maryland and explained the Licensing State concept in detail as incorporated in the prepared draft, Part C. Additional changes in the draft were made as a result of the Licensing State concept, as amended in Part C. The Chairman of the Conference was informed by telephone and letter of the TRC action.

On January 12, 1977, the Chairman of the Working Group met with the Conference's Executive Committee in Phoenix, Arizona to again discuss the Licensing State concept. The Executive Committee felt they could not take action on the TRC recommendation until a Conference legal review could be made regarding the Conference's constitution and bylaws. A letter was sent to the Conference Chairman, TRC Chairman, and the Conference Executive Secretary regarding aspects of concern. A copy of that letter is attached to this report.

On April 21, 1977, the Chairman of the Part C Working Group was again to meet with the Executive Committee of the Conference in Oklahoma City on the Part C draft and the Licensing State concept. Unfortunately, due to a Rocky Flats Plant situation in Colorado, the Working Group Chairman could not attend the Oklahoma City meeting and the matter is unresolved at this point in time.

January 18, 1977

Frank Wilson, Executive Secretary
Conference of Radiation Control Program Directors
4815 W. Markham Street
Little Rock, Arkansas 72201

Dear Mr. Wilson:

In accord with the Executive Committee's wishes the following is submitted:

The suggested change to Part C of the SSRCR to include the "Licensing State" concept may require the Conference to:

(a) establish criteria to be used in the evaluation of the respective programs;

(b) provide a mechanism to perform the evaluation;

(c) make a determination as to the acceptability of a state program in accord with the established criteria;

(d) establish an appeals procedure should a state feel the evaluation and determination decision inappropriate

If the Conference decides to accept these responsibilities, what problems of an untenable nature could arise regarding but not limited to:

(a) The legal limits of the Conference's Constitution, Articles of incorporation, contracts with other agencies, etc?

(b) What is the authority for adoption of a national policy?

(c) How does one approve the credentialing of the evaluators?

(d) How and where should the acquired determination be published? What should be the content of that statement?

(e) What liabilities are involved with such actions?

It is this writer's opinion that in the absence of federal authority in this matter, the Conference's leadership role in radiation matters, the voluntary nature of the proposal, and the positive step toward a uniform regulatory effort as provided by the proposal, the Conference will accept some "liability" if it does not move to promote this concept. Should a state, for whatever reason, not become a "Licensing State," the situation would be handled as it currently is--piecemeal. Under the "Licensing State" concept the only change would be a broader acceptance of that state's license's authorizations and a more uniform national regulatory effort to the betterment of all.

It must be also pointed out that the current agreement states will gain little from the proposed action. It is the non-agreement states that will benefit the most.

Should you require additional input, please advise.

Sincerely,

ORIGINAL SIGNED BY
A.J. HAZLE

Albert J. Hazle, Director
Occupational and Radiological
Health Division

AJH:jas

TASK FORCE NO. 6

SUGGESTED STATE REGULATIONS

PART K - NUCLEAR PHARMACY

Lynn A. FitzRandolph, Chairman - Arizona Atomic Energy Commission

The Radiopharmacy Task Force met in Rockville, Maryland on April 25, 1977, at the Bureau of Radiological Health. The American Pharmaceutical Association, Section on Nuclear Pharmacy (APhA), was represented by two individuals, as was also the National Association of Boards of Pharmacy (NABP). The State Radiation Control Programs were also represented by two persons and the U.S. Nuclear Regulatory Commission (NRC) by three persons from NRC staff plus one consultant to NRC. The Bureau of Radiological Health and the Environmental Protection Agency each had representatives at the meeting. For the afternoon session we also had expert advice from the FDA's Division of Oncology and Radiopharmaceutical Drug Products as well as from EDRO. The following prospective participants were not in attendance:

Mr. Robert Will of the Washington State Radiation Control Program,
Mr. David Lacker of the Texas Radiation Control Program,
Dr. James Martin of the Environmental Protection Agency, and
Mr. Elmer Eisenhower of the National Bureau of Standards.

The pharmacists in attendance preferred the use of the term "Nuclear Pharmacy" over the term "radiopharmacy;" therefore, the term "Nuclear Pharmacy" will be used throughout the remainder of this report.

Nuclear Pharmacy is in an early stage of development and its future development appears to depend upon two concerns, which are within the purview of this Task Force: (1) Development of a model State regulation to which the State Boards of Pharmacy and also the State Radiation Control Programs can relate in their respective regulation and licensure of Nuclear Pharmacy activities; and (2) clarification of the roles and responsibilities of the NRC, the FDA, the State radiation control programs and the State Boards of Pharmacy. The State Boards of Pharmacy, as represented by the National Association of Boards of Pharmacy, appear to be of the opinion that the State radiation control programs and NRC should regulate only the public and radiation safety aspects of the nuclear pharmacy activity and not get into areas they feel fall strictly within the practice of pharmacy. The NRC will not be in a position to state an opinion in this context, beyond their current policy of working closely with FDA, at least until after their public meeting of May 6, 1977 (as noticed in the FEDERAL REGISTER of Thursday, April 21, 1977). The American Pharmaceutical Association representatives would appear to agree with the position expressed by the National Association of Boards of Pharmacy representatives to the point that State radiation control agencies and the NRC should not be regulating certain activities they believe to be strictly the practice of pharmacy. Representatives of both groups would appear to imply that the radiation control programs of the States and the NRC have, in the past, been impinging upon the practice of pharmacy. The NABP and the APhA appear to be concerned that we radiation regulatory agencies are continuing outdated licensing and regulatory policies that predate the FDA's withdrawal of exemption for radiopharmaceuticals, which exemption was issued to the U.S. Atomic Energy Commission in 1963. No one at the meeting gave an opinion in favor of such a philosophy.

The Chairman's "Discussion Draft One" dated February 1977 was written in order to bring together regulatory concepts he felt needed discussion. The opinion of the Chairman is that additional regulations are not needed in the area of public and worker radiation safety aspects of nuclear pharmacy. Almost all participants in the meeting had had the benefit of an advance copy of this draft. From the discussion at this meeting it was apparent that these draft regulations were, indeed, to the point and quite complete as to the general concepts of interest and/or concern of the various groups represented. These draft regulations were not directly discussed, point by point, as it rapidly became apparent that there was almost no support at this time, within the group, for developing suggested State radiation control agency regulations along the lines of this draft. However, another draft that had been developed by the NABP using the Chairman's Discussion Draft One as the framework was discussed at the meeting with certain revisions suggested by the participants. This latter draft titled "Nuclear Pharmacy Regulations proposed by NABP Subcommittee, April 16, 1977, Phoenix, Arizona," with changes recommended by the Task Force, is attached. The NABP's draft was presented to our group by Rodney D. Ice, Ph.D., representing the NABP. It was developed by an NABP subcommittee of 6 members, meeting with the Chairman in Phoenix, Arizona on April 15 and 16, 1977, at the behest of the NABP, and is intended for presentation at the 73rd annual meeting of the NABP, in St. Louis, on May 21 to 25, 1977. The NABP appears to feel strongly that they should proceed along these lines, and the radiation control programs should not.

Those items of concern that appeared in the Chairman's "Discussion Draft One," but not appearing in the NABP draft were discussed at considerable length at this Task Force meeting. These items will be described later in this report.

Part of the charge to this Task Force was to review and evaluate the impact of nuclear pharmacy upon existing regulations. There are two bodies of regulations that are possibly impacted. The first is Pharmacy Board regulations, and the second is Radiation Control Agency regulations. The pharmacy representatives at this meeting appear to be of the opinion that the existing pharmacy statutes of the several States, as well as regulations developed under such statutes, are adequate and compatible to the concept of adding regulation of nuclear pharmacy through the respective boards of pharmacy. The NABP feels that all that is needed is: (a) model regulations, for the NABP model State regulations, along the lines of their draft proposal; and (b) clarification of policies and procedures among the radiation control agencies. With respect to the existing State radiation control model regulations, two existing sections with possible impact were brought out and discussed. The first was Section C.40 - transfer of material; specifically, C.40(b)(4). In the context of this subparagraph, Mr. Leo Wade of the NRC stated that the factor in regulating the transfer between a nuclear pharmacy and, say, a nuclear medicine program, in the common case of both licensees being authorized to possess the same chemical and physical form, would be licensing conditions placed upon the two respective licenses. In this light, then, the radiation control regulation of nuclear pharmacy activities, would appear to depend very strongly upon the use of appropriate and carefully worded licensing conditions by the radioactive materials licensing agency involved. In the opinion of the Chairman, this would entail written licensing guidance to the States from the NRC. The Chairman stated this opinion at the meeting, but the NRC representatives were not in any position to concur with this opinion at the time of the meeting.

The second area of possibly impacted State model regulations is Paragraphs C.28(j) and C.28(k) dealing with manufacture and distribution of radiopharmaceuticals for use under group licenses. These sections are relevant to the regulation of nuclear pharmacy if such pharmacy activity involves distribution of materials to group medical licensees, although the pharmacists would argue that they do not necessarily "manufacture and distribute"--which is a phrase used in said sections. Two items are of interest here. First, subdivision C.28(j)(1)(ii)(b) and 10 CFR 32.72(a)(2)(ii) state that the applicant may submit evidence that "the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food Drug and Cosmetic Act and the Public Health Service Act." As developed at this Task Force meeting this is clearly impossible, since no one involved with radiopharmaceuticals is exempt from all provisions of said Acts. This subdivision, which also appears in C.28(k) and 10 CFR 32.73, is of no avail in nuclear pharmacy licensing and regulation and since it is also impossible it could and should be deleted from the State and NRC regulations in both places.

The second point of concern here relates to Section C.26(c) groups of diagnostic uses. Within those groups appear uses on IND. Despite this it is, or has been, a licensing policy of NRC not to authorize nuclear pharmacies to dispense IND materials obtained from commercial supplier/sponsors of IND's. Mr. Wade of the NRC stated that this policy was developed in consultation with the Food and Drug Administration and is implemented through NRC licensing conditions for nuclear pharmacies. The FDA representatives at the meeting took exception to this position and stated that there must be some misunderstanding. Considerable discussion ensued upon this particular point at which time it was deferred until the afternoon session in order that we could have representation available from the Division of Oncology and Radiopharmaceutical Drug Products, FDA to address this issue. During the afternoon session the matter was resolved, apparently to Mr. Wade's satisfaction. This apparently resolved the issue, but again, in the opinion of the Chairman, the NRC needs to develop some definite written guidelines to help the States with licensing policy and correct license condition phraseology in this area.

Some discussion took place on the concept of providing a regulatory distinction between classes or types of nuclear pharmacies: for example, hospital-based pharmacies as distinguished from commercial or independent nuclear pharmacies. Another example would be a distinction between a pharmacy in a large medical research institution, perhaps possessing a broad radioactive materials license, in comparison with a smaller hospital pharmacy. No support was brought forth at this Task Force meeting for such a concept. It should be noted that there is in the draft regulations of the NABP an exemption for medical practitioners. This exemption is intended to reflect the pharmacy statutes and the medical practice statutes of the several States, and would appear to exempt from pharmacy regulations private physician offices and hospital nuclear medicine departments to the extent that they are preparing and administering radiopharmaceutical agents within the confines of their office or department. Although it is the Chairman's impression that the various State Boards of Pharmacy regulate hospital pharmacies in differing degrees, it is also the Chairman's impression that statutory authority to define those practices and procedures that are subject to pharmacy board regulation, as well as statutory authority to distinguish between any possible classes of pharmacies, is already embodied in the pharmacy statutes of the several States and, therefore, is probably not subject to regulation by radiation control agencies. Furthermore, any definition of the term "manufacturer" is the responsibility of the U.S. Food and Drug Administration, although model nuclear pharmacy regulations can and have been developed in the absence of an explicit distinction between definitions of the practice of nuclear pharmacy and manufacturing procedures.

The remaining basic differences between the Discussion Draft One and the model regulation proposed by the NABP appear in Section K.3(i) of the former. Section K.3(i) provided that unless the nuclear pharmacy had specific conditions granting additional authority on their radioactive material license, a nuclear pharmacy (1) should dispense only in unit dose form; (2) should not dispense IND drugs; (3) should use only drugs manufactured by FDA suppliers; (4) should not compound any drug from its basic ingredients; and (5) should not distribute drug kits including in vitro test kits, nor nuclide generators, other than in an unprocessed form with nonviolated product packaging as received from an approved supplier. There was no support in the committee for any of these items, with the possible exception of certain items being considered appropriate and desirable Radiation Control Agency concerns by one of the State radiation control persons in attendance at this Task Force Meeting. NABP is specifically opposed to these five items. The concept of unit dose dispensing gave way to dispensing upon prescription only, which implies an individual patient, and distribution for "office use only." The dispensing of IND drugs has been discussed above. The source of drugs used in the practice of pharmacy and the compounding from "scratch" are considered to be squarely within the practice of traditional pharmacy. The distribution of drug kits and nuclide generators can be performed in compliance with statutes and regulations of the FDA, although the distributor must be cognizant of the adulteration and misbranding provisions and manufacturing provisions of the FDA statutes and regulations, as indeed such person must be with respect to most of these five items.

Relevant here is a discussion of sponsorship of an IND. According to FDA representatives at this meeting, an IND may be sponsored by a commercial manufacturer or a nuclear pharmacy or the user-physician. Drugs used must come under (1) an NDA, although the user-physician need not be restricted to the labeling of a drug which is the subject of an approved NDA, with respect to indications for use, dosage, and other matters that are within the responsibilities of medical practice; (2) in accordance with an accepted IND; or (3) be approved for certain research uses in accordance with FDA regulations.

The FDA apparently has numerous physician-sponsored accepted IND's on file and, according to FDA representatives at the meeting, they have never terminated one of these on account of passage of time since acceptance of the IND. It should be clear that there will be instances when the filing of an IND by either a pharmacy or the physician will be necessary. Given the existence of FDA regulations in this regard it did not appear to the committee that this particular matter was within our purview, although one State radiation control agency member in attendance would disagree.

Following the discussion of the five items of Section K.3(i) of Discussion Draft One, members of the committee were asked if there were further items of concern which should be addressed in any model nuclear pharmacy regulations. There were none. The committee was then asked if it was of interest to draft out some nuclear pharmacy regulation requirements from the standpoint of public and worker radiation safety aspects. It was felt that this is already adequately covered in the existing model State radiation control regulations. There being no further business to come before the committee at this time, the meeting was adjourned with the understanding amongst the members that the NABP's annual meeting in St. Louis would have a presentation of the NABP's draft regulation for nuclear pharmacy. Task Force 6, Part K, awaits further guidance and instructions from the Healing Arts Council.

ATTACHMENT

NUCLEAR PHARMACY REGULATIONS

Proposed by NABP Subcommittee
April 16, 1977, Phoenix, Arizona

1. PURPOSE AND SCOPE

It is unlawful to receive, possess or transfer radioactive drugs, except in accordance with (cite appropriate pharmacy statute(s)). It is also unlawful for any person to provide radiopharmaceutical services unless he is a pharmacist or a person acting in accordance with (cite appropriate pharmacy statute(s)) (and) the State Board of Pharmacy regulations and regulations of the (cite appropriate State radiation control agency), with the exception of a medical practitioner (or other appropriate statutory terminology) for administration to his patients as provided in (cite appropriate medical practices statute). No person may receive, acquire, possess, use, transfer or dispose of any radioactive material except in accordance with the conditions of any radioactive material license required by the (cite radiation control agency) pursuant to (cite radiation control statutory authority). The requirements of these Nuclear Pharmacy Regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Radiation Control Agency.

2. DEFINITIONS

A. "Nuclear Pharmacy" is a pharmacy providing radiopharmaceutical services.

B. "Radiopharmaceutical Service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

C. "Radiopharmaceutical quality assurance" means, but is not limited to the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

D. "Internal test assessment" means, but is not limited to, conducting those tests of a quality assurance necessary to insure the integrity of the test.

E. "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

3. GENERAL REQUIREMENTS FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

A. The application for a permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist is responsible for all operations of the licensed area and shall be in personal attendance at all times that the pharmacy is open for business. In emergency situations, in the pharmacist's absence, he may designate one or more other qualified licensed professionals to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

B. Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The nuclear pharmacy area shall be separate from the pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 sq. ft. of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance and office area. A nuclear pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the State Board of Pharmacy. Detailed floor plans shall be submitted to the State Board of Pharmacy and the Radiation Control Agency before approval of the license.

C. Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

D. Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with (cite appropriate pharmacy and radiological control agency).

E. Nuclear Pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing non-radioactive drugs.

F. Radioactive drugs are to be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. *A pharmacy also may furnish radiopharmaceuticals for office use to practitioners for individual patient use.

**G. A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with (cite appropriate regulations of the radiological control agency).

H. In addition to any labeling requirements of the State Board of Pharmacy for non-radioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with: (1) the standard radiation symbol; (2) the words "Caution-Radioactive Material;" (3) the radionuclide; (4) the chemical form; (5) the amount of radioactive material contained, in millicuries or microcuries; (6) if a liquid, the volume in cubic centimeters; and (7) the requested calibration time for the amount of radioactivity contained.

I. The immediate container shall be labeled with: (1) standard radiation symbol; (2) the words "Caution-Radioactive Material;" (3) the name, address and telephone number of the pharmacy; and (4) the prescription number.

J. The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

K. Nuclear pharmacies may redistribute NDA-approved radiodrugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

---

* Denotes change in reading

** One sentence was deleted from the original

4. GENERAL REQUIREMENTS FOR NUCLEAR PHARMACISTS TO OBTAIN A NUCLEAR PHARMACY PERMIT.

A qualified nuclear pharmacist shall:

A. Meet minimal standards of training for Medical Uses of Radioactive Material (cite radiological control agency licensure guide)

B. Be a currently licensed pharmacist in the state

C. Have received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy

D. Attain a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an accredited College of Pharmacy

E. Submit an affidavit of experience and training to the State Board of Pharmacy

5. LIBRARY

Each Nuclear pharmacy shall have access to the following reference books. All books must be current editions or revisions:

A. United States Pharmacopeia, with supplements

B. National Formulary, with supplements

C. State laws and regulations relating to pharmacy

D. State and/or Federal Regulations governing the use of applicable radioactive materials.

E. United States Public Health Service, Radiological Health Handbook

6. MINIMUM EQUIPMENT REQUIREMENTS

A. Laminar flow hood

B. Dose calibrator

C. Refrigerator

D. Class A prescription balance or balance of greater sensitivity

E. Single channel scintillation counter

F. Microscope

G. Autoclave, or access to one

H. Pyrogen oven, or access to one

I. Portable radiation survey meter capable of detecting 0.005 microcuries of the radionuclides in question

J. Other equipment necessary for radiopharmaceutical services provided as required by the Board of Pharmacy

TASK FORCE NO. 7

NATURAL RADIOACTIVITY CONTAMINATION PROBLEMS

L. Hall Bohlinger, Chairman - Louisiana
Gary F. Boothe - Oregon
Dayne H. Brown - North Carolina
Michael Christie - Idaho
Ulray Clark - Florida
Richard J. Guimond - EPA

Task Force No. 7 on Natural Radioactivity Contamination Problems was established by the Executive Committee of the National Conference of Radiation Control Program Directors in 1975 as an extension of Workshop No. 5 of the 1974 Annual Conference, and consists of the above members.

The charge to this Task Force is to:

1. provide assistance to the Conference, individual States, and Federal agencies in scoping the problem of contamination by natural radioactivity;
2. assist in developing appropriate radiation protection guidance and criteria;
3. assess the impact of naturally occurring radioactivity contamination in the general environment and the Conference member states; and
4. serve as a focal point for State input to the programs of Federal agencies.

The charge given necessarily implies certain responsibilities in which the Task Force must assist the appropriate State and Federal agencies. These include the following:

1. defining the radiation level or concentration or stage of processing in which naturally occurring radioactive material (NORM) becomes a contamination to the environment;
2. identifying who has the authority to develop and implement guidelines and criteria for enforcement action;
3. identifying the impact that naturally occurring radioactive contamination has on the general population;
4. examining the need for controls on the use of products and byproducts containing NORM and the associated economic impact of such control.
5. defining the sources currently known or suspected to contain possibly hazardous amounts of NORM and describing other potential problem areas; and
6. recommending priorities for control programs to address NORM problems.

Natural radioactivity and its associated radiological impacts have generally been overlooked in the past. Although there have been strict controls on other sources of radiation such as byproduct material, x-ray machines, special nuclear material, and so forth, natural radioactivity control has been minimal, perhaps because it is "natural" rather than "manmade" radioactivity. This lack of strict controls has been due in part to the fact that the Federal

Government has limited jurisdiction over naturally-occurring radioactive material, and control was left previously up to the States, who often times did not have adequate programs to deal with radiation. While there are over 100 naturally occurring radionuclides, public health problems are usually limited to the 30 or more radionuclides in the uranium and thorium decay series because of their relative abundance and toxicity. The increased incidence of bone cancer in radium dial painters and lung cancer in fluorospar and uranium miners are examples of undesirable health impacts because of exposure to these radionuclides. Other examples of increased population exposure to NORM include the radon problems in several Western States resulting from the use of radioactive tailings and the use of reclaimed phosphate mining land in Florida.

The majority of the work of this Task Force does not deal with what is usually referred to as truly natural radiation exposure, but more appropriately is concerned with exposure to radiation occurring as a result of alteration of the natural sources by technology. This new category for human radiation exposure, introduced by Gesell and Pritchard, is termed "technologically enhanced natural radiation" (TENR), and is defined as "exposures to truly natural sources of radiation (i.e., naturally occurring isotopes and cosmic radiation) which would not occur without (or would be increased by) some technological activity not expressly designed to produce radiation." Thus, exposure to increased radiation from living in a structure constructed over phosphate mining reclaimed land would constitute a TENR exposure; however, an exposure from a radium needle would not since the latter is expressly designed to produce radiation. It is interesting to note the EPA in their May 1976 report, "Radiological Quality of the Environment" has estimated from the sketchy data available, that for individuals, the largest radiation dose received from all sources is derived from TENR. This results in 140 to 14,000 millirems per year to the tracheobronchial surface tissue of the lung, mainly as a result of inhalation of radon daughter products from uranium mill tailings. Additionally, the third largest category of population dose is estimated to be from TENR which contributes approximately 3 million person-rem per year internal exposure. This internal dose results from exposure to ore mining and milling, radon in potable water, natural gas, LPG, mines, caves, and in geothermal energy production, and radioactivity in construction materials. This is comparable to the dose received from the use of radiopharmaceuticals, which is the second largest category of population dose contributing slightly greater than 3 million person rem per year.

It is the objective of this Task Force to collect and study available information and data on naturally occurring radioactive materials in the environment and to make recommendations to the Conference regarding the need for evaluating, monitoring, and controlling natural radioactivity. The problem areas examined by the Task Force are as follows:

A. the phosphate industry;

B. the radiological aspects of thorium and daughter products;

C. radioactivity in fossil fuels;

D. radium and radon in ground water;

E. mineral extraction and processing activities;

F. radon in caves;

G. standards and guidelines for radioactive material concentrations in material and consumer products;

H. radioactivity in construction materials; and

I. statutory authority of States to regulate naturally occurring radioactive materials.

The Task Force has developed a series of recommendations based on findings and conclusion of data, and model State regulations have been developed for potential incorporation into the CSG Model State Regulations and adoption by those States where such action may be warranted.

During the past year and a half, the Task Force has met three times during which the Task Force members have toured the phosphate mining area of Central Florida and visited several housing projects built on reclaimed land in order to obtain a perspective on the magnitude of the problem. We have had the opportunity to tour a wet process phosphoric acid production plant, a uranium recovery pilot plant, review and compare a thermal process phosphoric acid production plant, and examine data on various structures in which thermal process slag was used in construction. Other relevant subject areas were discussed in detail and evaluations prepared independently by the membership. There are several items including naturally occurring radioactivity in livestock feed supplements and radium-226 in production brine discharges for which we are awaiting additional information and data before arriving at specific recommendations. Additionally, as requested by Dr. W. D. Rowe, Deputy Assistant Administrator, ORP, EPA, assistance is to be provided by this Task Force in the development of guidelines and criteria to be used in the assessment and regulation of products and materials containing naturally occurring radionuclides with particular emphasis on the indoor and outdoor uses of phosphate slag material in Idaho.

Based on our activities to date, the Task Force recommends the following actions be taken:

A. Pending the establishment of appropriate standards, the use of phosphate mining and milling byproducts in occupied structures should be discouraged if they contain elevated levels of radium-226. EPA should place high priority on evaluating this application of these byproducts and balancing this against the environmental problems associated with waste storage of the materials.

B. Phosphate byproducts, particularly gypsum, are presently used to a limited extent as an agricultural soil conditioner. Although little is specifically known regarding the environmental impact of this use, and considering the small addition of radioactivity to the environment, it is unlikely that this application would result in significant radioactivity uptake in crops. It is not recommended that this use of the byproduct materials be discouraged at this time. Additional controlled studies should be performed to document the anticipated minimal environmental impact of this use.

C. Slag from thermal process phosphoric acid plants should not be used for any purpose that results in its being placed under or within an enclosed structure. Any other use of slag should be thoroughly evaluated.

D. States, where applicable, should adopt regulations pertaining to control of radioactive mineral tailments and industrial byproduct piles. States should investigate their statutory authority over naturally occurring radioactive material and if necessary, enact appropriate legislation. Such suggested regulations are included in the Report.

E. The States should perform additional radiological air monitoring inside and outside phosphate plant areas.

F. States should inventory mineral mining and processing operations referred to in Part VI of this Report, and examine potential radiological aspects of their effluent, emissions, products and wastes. A report of the inventory and other findings should be submitted to Task Force No. 7 with any pertinent recommendations.

G. This Task Force as a representative of the Conference, should meet with EPA, NIOSH, OSHA, and MESA and discuss their respective jurisdictions and activities regarding occupational radiation exposure in the phosphate industry.

H. EPA should study the uptake of naturally occurring radionuclides in food crops from irrigation water, fertilizer, and radiation-bearing soil.

I. EPA should study the whole body and organ doses resulting from ingestion of radon daughters in drinking water.

J. EPA should evaluate the inhalation hazard that may result from the release of radon from water containing high concentrations of naturally occurring radioactive material during certain home and commercial uses.

K. EPA should develop national criteria and guidelines concerning the use and distribution of industrial byproducts containing naturally occurring radioactive material. The EPA should consider seeking appropriate authority to promulgate such guidelines as national standards.

L. EPA and appropriate States should study and evaluate all uses of fly-ash from coal-fired plants, particularly related to construction materials.

M. The radiological aspects of each proposed coal-fired plant should be evaluated by the appropriate agencies. Radioactive releases should be estimated from an analysis of the coal to be consumed and the operating characteristics of the proposed plant. This recommendation is especially pertinent to any proposed plant that intends to derive its fuel form low-grade, uraniferous Western coals.

N. The EPA should develop standard procedures and guidelines for sample collection and analysis of naturally occurring radioactive material to ensure the acquisition of uniform and comparable data by State and Federal programs. The EPA should expand their cross-check quality assurance program in conjunction with the standard analytical procedures and to include NORM.

O. The States, the EPA, or other appropriate agencies should proceed to measure radon levels on fly-ash piles and in structures built in fly-ash disposal areas, if such a case exists.

P. It is recommended that representatives of this Task Force, EPA, NIOSH, and MESA meet to discuss the preliminary investigations and measurements of radon-222 in caves and determine what other studies should be undertaken to properly evaluate this situation. Additionally, the interim recommendations made on the basis of existing Federal guidance for the protection of underground uranium miners should be evaluated as additional information and data are obtained.

Q. This Task Force recommends that a thorough evaluation be undertaken concerning the occurrence of radon-222 as a source of possible radiation exposure in state and privately owned caves.

R. In view of the measured high concentration of radium-226 in oil brines, the impact of uncontrolled discharge of these brines on the biosphere should be evaluated by appropriate State and Federal agencies. The proposed study in Attachment E to investigate this impact should be considered for funding by EPA or other appropriate agencies.

S. Phosphate industries and all other industries having significant radiological impacts should be licensed in order to assure adequate controls over naturally occurring radioactive materials.

In conclusion, on behalf of the membership of this Task Force, I would like to express our appreciation to the Conference for the support given to our work over the past year, and additionally to Rich Guimond, our Federal resource person for his valuable contribution.

TASK FORCE NO. 8

RADIOACTIVE WASTE MANAGEMENT

Heyward G. Shealy, **Chairman** - South Carolina
Tom Cashman - New York
William Horton - Nevada
Ted Wolff - New Mexico
David Clark - Kentucky
Robert Will - Washington
Pete Tedeschi - Illinois

George De Buchanamne - USGS
Shelly Schwartz - NRC
Bob Augustine - EPA
Gerald Daly - ERDA

The first Task Force meeting was held in Bethesda, Maryland, during September 21 and 22, 1976. Part of the meeting was devoted to updating members of the Task Force of activities at respective commercial burial sites, and a briefing by Federal agencies describing their work in waste management. Reports were presented by NUS and AIF that defined projected volumes of waste to be managed by the year 2000. Also, during the meeting it was agreed upon by Federal representatives and participating States that State representatives on the Task Force become involved and assist with the formulation of criteria and standards for burial grounds. This was in keeping with the scope of the Task Force. In addition, State Task Force members were assigned a specific area to research and work toward developing a solidification standard.

To facilitate work in this particular area, a second Task Force meeting was held in Vicksburg, Mississippi, during February 9 and 10, 1977. The meeting was coordinated with EPA and the U.S. Army Corps of Engineers Waterways Experimental Station.

During the Conference year, two workshops were held by EPA entitled "Issues Pertinent to the Development of Environmental Protection Criteria for Radioactive Wastes." The meeting was designed to obtain input from all sectors of society, government, industry, and the public in establishing criteria. An issues and objectives statement was issued by EPA prior to the meeting. The Conference Task Force was represented at each of the EPA meetings and contributed to workshop sessions.

A recent symposium entitled "Management of Low-Level Radioactive Waste" was held in Atlanta, Georgia. The conference made it possible for some members of the Task Force to attend and contribute to this symposium.

Increasing attention is being given to the problems associated with waste disposal. Consequently, we recommend that the Task Force on radioactive waste management be continued with emphasis on the following:

1. Provide continued input into the development of criteria and standards for radioactive waste management.

2. Continue to provide communications between State and Federal agencies to continually upgrade waste management procedures.

TASK FORCE NO. 9

ESTABLISHMENT OF SOIL CONTAMINATION LIMITS

A. J. Hazle, Chairman - Colorado
Ulrey Clark - Florida
Robert Will - Washington
Ted Wolf - New Mexico
Donald Ebenhack - South Carolina

This task force was established as a result of the Workshop Report on the same topic of the Eighth Annual Conference Meeting in Springfield, Illinois.

The Workshop Report delineates the need for such guidance and recommends that concerted effort be delayed until the Environmental Protection Ageney guidance on plutonium in soil is available because of the complexity of the consideration. It was hoped that the finalized version of that EPA guidance might be useful in developing similar guidance for other radioactive materials of concern. At the time of writing this report, that guidance is still not available for review by this Task Force. Hopefully, it will be available in the near future so that productive deliberations can ensue.

TASK FORCE NO. 11

PUBLIC HEALTH IMPACT OF NUCLEAR MEDICINE PRACTICE

Phil Brunner, Chairman - Illinois
Andrea Dwyer - New York City
Goldie Watkins - New York
Ron Forsythe - Mississippi
Jerry Allen - Kansas

Bart McIntyre - BRH
Harry Pettingill - EPA

INTRODUCTION

The use of radionuclides in the field of nuclear medicine has been accelerating in the United States at a rapid pace. In 15 short years since nuclear medicine practice began to develop, the frequency of nuclear medical diagnostic procedures has at least quadrupled according to best estimates.

Because the practice of administering radioactive substances (radiopharmaceuticals) to the human population has become almost commonplace, there is a vital need to accurately access the public health impact that this particular branch of diagnostic medicine represents. For this reason, the Conference of Radiation Control Program Directors, Inc. established a task force during FY 1976 - 1977 to define and quantify a reporting system to measure the population impact from nuclear medicine.

SCOPE OF TASK FORCE

Several studies have been conducted in recent years (BRH, JCAH, ACR, and SNM) that have attempted to define and quantify the extent of nuclear medicine practice. These studies indicate a continuing growth rate in numbers of procedures performed of about 25 percent per year. In order to access the public health impact, reliable information is required on the specific radiopharmaceuticals used and the radioactivity administered. While there are several sources of information with respect to procedure use, the Task Force determined at its St. Louis meeting in September 1976, that there was a relative lack of information in several vital areas:

1. The number of nuclear medicine procedures performed and the radiopharmaceuticals used.
2. Identification of trends in nuclear medicine procedures and radiopharmaceutical use.
3. Age specific use rates.
4. Range of administered doses per procedure and radiopharmaceutical.

The BRH/FDA has developed a reporting system which they have pilot tested at six designated hospitals. The system, MODS (Medically Oriented Data System) uses computer terminals in each hospital in which nuclear medicine data is inserted daily and is recalled by FDA on a scheduled basis. The MODS program was developed to collect medical device experience and drug related injury data with information on nuclear medicine being a part of the entire program.

The Task Force at its St. Louis meeting affirmed the potential usefulness of MODS and supported efforts of the FDA to expand this program to additional facilities. In conjunction with MODS data, the Task Force also felt that State involvement in obtaining use data should be explored by at least two methodologies; mailed questionnaires to State licensees and data gathering by State inspectors during routine inspection activities. This dual approach actually evolved because New York representatives, in particular, felt that inspector-generated data could not be sold in their State with their current workload commitments. The testing and comparison of the two approaches did have a favorable reaction to the Task Force, since effectiveness of both methods could be evaluated.

The field inspector data gathering program, as proposed, would consist of a computer compatible form (similar in structure to NEXT forms) and necessary instructions to enable the inspector to obtain the information in a rapid, yet effective way. Data forms would then be sent to the Illinois Health Department for insertion into a computer and for manipulation purposes.

SUMMARY

Since the Task Force's last meeting, the MODS program of BRH has been expanded; the mailout questionnaire has been mailed out in New York, the form distributed to licensing States; and the State inspector form was distributed to all Licensing States. During this meeting in Seattle, the Task Force is reviewing data that has been generated from eight participating States and from the questionnaire mailout in New York.

It is the Task Force's opinion that our initial efforts have been fairly well accepted and it is hoped that the Conference will consider future development of these data gathering programs.

TASK FORCE NO. 12

EMERGENCY PLANNING

Margaret A. Reilly, **Chairman** - Pennsylvania
Sherwood Davies - New York
Aubrey Godwin - Alabama
David Snellings - Arkansas
John Stanton - New Hampshire
Robert Wolle - Tennessee
Gary Wright - Illinois

The scope of the Task Force activities was assigned by the Conference Chairman as follows:

> **Scope:** Delineate and make recommendations concerning the needs of State and local radiation control programs in the area of emergency response planning and training, particularly as they pertain to the following:
>
> 1. Actions of the Federal Interagency Central Coordinating Committee for Nuclear Incident Emergency Planning at Fixed Facilities and for Transportation.
> 2. On-going and planned training courses for State and local personnel in all aspects of emergency response planning.
> 3. The modified cadre (steering committee) approach to assisting agencies in emergency response planning.
>
> And review existing and proposed guidance for effectiveness in addressing the specific problems, practical feasibility, and impact on State radiation control programs.

The Task Force met formally twice during the year. Several members also met informally in the course of an ACRS Subcommittee (Environmental) meeting in April.

The initial activity of the Task Force was the identification of those elements in NUREG-75/111, the Guide and Checklist, which we believed to be essential. The criteria we used for rejection of original elements included (1) elements dealing with procedural matters, (2) elements applicable only to trans-DBA accidents, (3) elements pertaining to general emergency planning, and (4) elements dealing with accidents other than at fixed facilities. We listed the elements believed essential and sent the list to NRC-OSP.

The Supplement to the Guide and Checklist was published in mid-March. The Supplement retained several elements that pertain to trans-DBA accidents. Since several of us have concerns regarding the magnitude of the planning accident, the retention of those items precipitated some individual comment to OSP.

This matter of the magnitude of the planning accident is currently under consideration by an NRC-EPA interagency review group. It appears that the Conference Task Force has no appropriate actions available to it pending the outcome of the NRC-EPA deliberations. OSP has indicated that the Task Force will be invited into the discussions following the development of a preliminary senario.

In addition to the question of accident magnitude, concern has been manifested over the Supplement 1 requirement that drills critiqued by an Interagency Cadre will be required to achieve initial concurrence. Further, a critiqued drill may well be necessary on an annual basis in order for a State to maintain concurrence. No one will take issue with the need for annual drills. There is some question though as to whether sufficiently qualified Cadre personnel are available to critique these drills, particularly east of the Mississippi. It should be indicated that the Task Force was aware only of the intent to revise the list of elements in NUREG 75/111 and had no knowledge of the content of the narrative accompanying the revised list of elements in Supplement 1.

At the January meeting of the Task Force we discussed Federal training activities related to training for emergencies, the draft FDA guidance for food contamination, and instrumentation for radiation emergencies. We also attended a meeting of the Federal Central Coordinating Committee.

Training

The Federal Interagency Task Force on Training and Exercises has established eight categories of training for radiation emergencies at fixed nuclear facilities from "first on the scene" through "high level decision makers." (The description of the training categories and their order priority were given with the report of the January meeting.) The Conference Task Force is of the opinion that Categories I, II, and III for "first on the scene," "paramedicals," and emergency room personnel," respectively, should be set aside regarding power plant accidents. The development and delivery of these categories of training suggest to us that we should, in the case of Category I (first on the scene), prepare police and firemen and other volunteer and service groups, to take radiation measurements for the evaluation of offsite consequences of a reactor accident. Few, if any, States plan to call on these people for that purpose. In the case of Category II and III (paramedicals and emergency room personnel) the delivery of this training suggests the likelihood of offsite radiological casualties; a condition that transcends the consequences of a Design Basis Accident. These categories will be developed and delivered to the States, who in turn have the option to accept or reject these packages.

Our Task Force is of the opinion that, in planning and training, emphasis should be placed on squaring away the State radiation control groups before attending to county and local governments. This would place emphasis on Categories IV and VI for response teams and decision makers. Categories VII and VIII for decision authority and protective action implementors should be consolidated into Category VI, since in many cases they may all be the same person.

Contamination of Food Supplies and FDA

Our Task Force continues to be concerned in the matter of contamination of food supplies, as a result of reactor accidents particularly the case of fresh fluid milk contamination by radioiodines. We consider this consequence to be of reasonable probability; of much greater probability than any event requiring protective actions against immersion and inhalation. Experiences resulting from the October fallout episode further reinforced concerns regarding the need for suitable guidance.

We met with representatives of FDA regarding the draft guidance. We experienced difficulty in reaching a consensus for developing Task Force comments on the draft guidance. Members were encouraged to submit individual comments to FDA directly.

In addition to the development of final FDA guidance, we see much unfinished business in the area of protection of fresh fluid milk supplies.

The protection of this commodity will require substantial attention to the logistics of sampling, analysis, and distribution conditions that do not appear to be realized in the radiation protection community. The importance of identifying methods of avoiding the contamination of the product and minimizing the consequent financial penalties to the dairy farmer must be appreciated.

We see a need for the development of sensitive radioassay techniques for milkborne radioiodines suitable for field use. Training for this accident consideration would be highly appropriate.

Emergency Instrumentation and EPA Manual Draft Appendix D

We met with representatives of EPA/ORP for discussion of this item. We commented on some of the instrumentation assumptions particularly in the matter of instrument sensitivities and response characteristics.

The Chairman and Aubrey Godwin also met with the Federal Interagency Task Force on Instrumentation in March. It was evident that the activities of this Task Force could have benefited from early identification of the magnitude of the accident to be planned for as well as an understanding of the workings of State and local government.

Federal Central Coordinating Committee

We attended a regular CCC meeting. Task Force representatives reemphasized the need for a planning and training accident, not only for state planning needs, but also to allow a systematic approach for the Interagency Task Forces on Training and Exercises, and on Instrumentation. We encouraged the establishment of some line of continuity between the Interagency Task Forces.

Several Task Force members met informally in the course of a meeting of the ACRS Environmental Subcommittee in April. Mention was again made of some of our continuing concerns.

RECOMMENDATION

1. Since, according to Supplement 1 to NUREG-75/111, the list of essential elements, and presumably the narrative, will be open to revision on an annual basis, it is recommended that the Task Force develop a revised list of elements and other appropriate commentary in anticipation of the next revision.

2. The Conference should continue to press for the identification of the accident to be planned for, until the issue is satisfactorily resolved.

3. The Task Force should continue its activities with the Federal Interagency Task Force on Instrumentation and on Training and Exercises toward providing some continuity among the Task Forces as well as toward the better understanding of State government operations and organization by Federal representatives.

4. The Conference should press for the focusing of attention by State and Federal government on the resolution of problems related to protection of fresh fluid milk from radiocontamination in the wake of a nuclear power station accident.

TASK FORCE NO. 13

NOTIFICATION PROCEDURES FOR RADIOACTIVE SHIPMENT

Leonard R. Solon, Chairman - New York
(presented by Arthur T. Heubner, Connecticut)

At the meeting in Springfield, Illinois last year, we agreed with the concurrence of the President-Elect, to defer substantive further action of a Conference Transportation Committee to await the results of the **Nuclear Regulatory Commission/Sandia Task Group on Transportation of Radioactive Materials in Urban Environs** which was just getting started and which included Conference members as participants.

The NRC/Sandia Task Group has held meetings in New York City; Arlington, Virginia; Baltimore, Maryland; and will meet again in Houston, Texas in July. It is reasonable to expect that this broadly-based and very competently directed Task Group will emerge with scientific data that is extremely useful in the radiation control area. However, there are questions of public health and public policy which will probably not be treated in depth by the Task Group and I recommend that the Conference activate its own Transportation Committee to treat such detailed matters as:

1. Notification procedures to states and local jurisdictions for shipments such as spent-fuel, plutonium, and high-level waste.
2. Emergency training of drivers and couriers.
3. Recommendations for labeling revisions where indicated.
4. Recommended routes for large sources.
5. Public education regarding source shipments.
6. Status of classified shipments.
7. Problem areas of specific states and local jurisdictions.

To this end, I would suggest that the Conference obtain adequate funds for two meetings of the Transportation Committee during the year preceding the next annual meeting.

TASK FORCE NO. 14

QUALITY ASSURANCE

Chuck Hardin, **Chairperson** - Kentucky
Murray Neuweg - Illinois
Gene Fisher - New Jersey
Bob Craig - Oklahoma
Beattie DeBord - West Virginia

Dick Gross - BRH
Charles Showalter - BRH
DeVaughn Nelson - EPA

INTRODUCTION

This Task Force on Quality Assurance was formed after our meeting in Springfield. For clarification, since quality assurance can apply to many different areas, the charge to this Task Force, at least initially, relates only to quality assurance in the field of diagonstic x ray. The specific charges given to this Task Force by the Executive Committee are as follows:

1. To define the areas that use diagnostic x rays that require quality assurance and to describe the basic factors to be included in quality assurance programs.

2. To examine current diagnostic x-ray quality assurance programs in Federal agencies and serve as a focal point for State input into these programs.

3. To report to the Conference on quality assurance programs and techniques that could be utilized by the State radiation programs.

The Task Force met in December, in March, and in May. Before going into the specific activities, goals, and accomplishments of this Task Force, I would like to give some rationale as to why the Executive Committee of the Conference and, in particular, this Task Force feel there is a need for quality assurance in diagnostic x ray.

First of all, there probably is some misunderstanding relative to the term quality assurance. The definition adopted by the Task Force is defined as follows:

> Quality Assurance (QA) means the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality radiographs at minimum cost and minimum patient exposure.

My personal preference of the proper term for what our Task Force is striving to provide is what several States call "action programs" in diagnostic x ray. So while the identified name of the Task Force is "Quality Assurance," the more appropriate words as applied to a State radiation control program would be "Task Force on Action Programs in Diagnostic X Ray." What do I mean by the words "action program?" It is activities implemented by a State radiation control program that will result in the reduction of radiation dose, primarily to the patient, by certain methods and procedures that are not necessarily covered by regulations. Most States presently have regulations that establish standards of good health safety regarding certain aspects of the x-ray equipment, darkrooms, protection for the operator, protection of the patient, and protection of the environs. These established regulations address specific areas in which radiation dose reduction can easily be demonstrated when followed by the x-ray user. However, there are many areas in which certain actions can be taken by a State radiation control program that will result in dose reduction that do not relate to enforcement of regulations. In some cases, these noncompliance actions, or "action programs," may result in greater dose reduction than by compliance actions. Specifically, several studies have been done on the retake rate at diagnostic x-ray facilities. These studies have shown that the retake rate may be as high as 15 percent. For every radiograph made in which a retake is required, the exposure to the patient has in essence doubled. An action program to reduce the number of retakes, therefore, can have significant impact on the reduction of radiation to the patient. In addition to this vital area of dose reduction to the patient, a quality assurance program will also result in improving the image quality of the radiograph, therefore, possibly providing more diagnostic information to the physician. Additionally, a quality assurance program can result in the production of consistent images between different machines and auxillary equipment within the same facility. For example, experience has shown that in many facilities with several radiographic rooms, there is a lack of reproducibility in image quality from one radiographic room to another. A quality assurance program should result in more consistent images throughout the entire facility.

But the most important advantage of a quality assurance program, at least from the acceptance viewpoint of the user, is the reduction in the retake rate. For a large multi-purpose diagnostic x-ray facility, it is not uncommon for the budget to be approximately $1,000,000 per year. If that particular facility had a retake rate of 10 percent and the initiation of a quality assurance program resulted in 4 or 5 percent reduction in retakes, the facility will have saved up to $50,000 a year. If this can be adequately demonstrated to the facility, we should have no difficulty in introducing quality assurance to the facility. The result would be a savings to the facility, while reducing dose to the patient.

Some of you may be thinking that a quality assurance or "action program" for your State is not appropriate. I would like to pose three questions to the State program directors and have each of you mentally answer them with a yes or no. The questions are as follows:

1. Should I discontinue routine and thorough compliance re-inspections of a facility if only very minor items of noncompliance have consistently been found after several years of inspections?

2. Do I have facilities that may meet all the regulations, but constantly exceed some established guidelines on entrance skin exposure? An example of suggested guidelines for such comparison would be the third quartile of NEXT data based on the national average.

3. If I knew the retake rate of facilities within my State, can I cause a substantial change in the retake rate by methods other than by compliance actions? More importantly, do I feel that actions that are not necessarily compliance actions may in fact be more effective in reducing retake rates than by compliance actions?

If you answered yes to any of the above questions, QA or "action programs" may indeed be appropriate for your program.

One other clarification is needed before going into details of the activities of this Task Force. Obviously, the only permanent, effective quality assurance program for an x-ray facility is a program adopted to be used regularly by that facility. Therefore, the primary objective of any activities performed by a State radiation control program in QA is to ultimately have the facility initiate and use the QA program within that facility. However, there are specific actions that can be taken by a State program that not only can be used to convince the facility of the need of initiating a quality assurance program, but simultaneously provide for that facility a service in identifying a specific problem that can result in improved image quality, financial savings, and dose reduction. It is these specific actions by the State program that fall into the category of "actions program." In the implementation of QA activities by a State radiation control program several approaches can be taken. The State program may only want to participate in a mailout project, which will involve a few man hours of time. Another option is to designate one x-ray inspector to be a "quality assurance expert" and have him perform all the direct "action programs" at the facility. A third option is for each one of the x-ray inspectors within the program to be trained in quality assurance and for certain identified facilites, perform a quality assurance "action program" in conjunction with compliance inspections. There may be other options that would be available in addition to the three which I have listed.

Now to specific activities, objectives, and accomplishments of this Task Force. In our first meeting in December, it was agreed that, to accomplish the charges, a manual would be developed and published by the Conference. This manual is to be designed to provide State radiation control programs with the information necessary for them to institute some type of QA activity if they so choose. It is the intent that this manual will cover a variety of subjects, including the identification and prioritization of those factors that will lead to image quality and/or exposure problems, and the determination of those radiographic procedures in which these problems are most troublesome. It will also describe the test tools and procedures that can be used during the facility surveys to identify the specific source of a facility's problems. In preparation of this manual, the Task Force has reviewed most of the activities performed by BRH relating to QA. This review included the results of the demonstration project conducted by the Bureau at a Public Health Service Hospital, and the results of the QA pilot study conducted in West Virginia.

The Task Force investigated the availability of QA programs from the radiographic industry. It was determined through this investigation that: (1) four x-ray film suppliers have quality assurance programs for their customers; (2) two test equipment suppliers have training programs for the use of their products; and (3) two manufacturers of major x-ray components have a QA program for their customers.

The Task Force also investigated the availability of QA services from private radiation consultants. It was found that there are consultants who offer a QA package to x-ray facilities. As one example, a survey performed in the State of New Jersey indicated that there were two basic types of QA programs available from consultants. The first is a complete QA program including preventive maintenance that costs the facility approximately $35,000 per year for a hospital with 10 x-ray rooms. The second was an "a la carte" program in which the charge was on an hour-by-hour basis.

The Task Force performed a review of the literature of various retake studies that were performed throughout the United States. This review yielded the following information:

1. Twenty-five to 50 percent of retakes are caused by inaccurate exposure (film too light or too dark).
2. Little work has been done on evaluation of processors as a cause for retakes.
3. Measured retake rates generally fall between 5 to 10 percent, on an average, although one study indicated the retake rate may be as high as 15 percent for one facility. One interesting aspect of this literature review was the indication that once the technologist within a facility is aware that a retake study is in progress, he or she begins to adjust to the study, so the results of any retake study may not necessarily be representative of the usual routine practice. The retake rate in practice may be higher than these results seem to indicate.

The Task Force also sent a questionnaire regarding QA to a representative sample of radiation control programs throughout the United States. The primary conclusions drawn from this survey were:

1. There appears to be a lack of understanding existing in the States as to the meaning of the term quality assurance in diagnostic radiography.
2. A QA program should be such that results can be measured rather than estimated.

3. There is more interest in States for QA in the medical area than in the dental area, perhaps because of the complexity of medical radiography.

One of the objectives of this Task Force is to obtain some definition from the radiology profession as to "what is a good radiograph." We all are aware that the definition of "what is a good radiograph" may vary from one radiologist to another. However, it is hopeful that some definition can be obtained that, at least, will include a range of acceptability from those practitioners who desire light films versus those who desire dark films.

So that the members of our Task Force would have some firsthand knowledge of the type of equipment that can be used in performing tests for QA activities, the Task Force devoted one full morning to a "hands-on" experience with typical test equipment.

In summary, it appears the main rationale for a State radiation control program to consider being involved in quality assurance programs, or "action program," is that, as it relates to the reduction of radiation exposure to the patient, we may be more effective in such dose reduction with actions that are an adjunct to our compliance and enforcement programs. It is important to note that I did not indicate that enforcement programs are not necessary, but action programs can be added that will be an adjunct to these enforcement programs.

The activities performed by this Task Force were an attempt to obtain the most current information available regarding QA activities in the United States. Our investigations have not only included what is being done at the Federal level, but what is being done by industry, by private consultants, and by a representative number of States. We feel that this investigation is most important, so that our efforts are not in duplicate of other efforts that are being made.

It is the objective of this Task Force to develop a manual that will provide State radiation control programs with a useful method of taking actions, not necessarily compliance actions, which will:

1. Reduce patient exposure.
2. Improve radiographic image quality.
3. Reduce costs of radiographic health care.

It is hoped that this manual will assist the State in:

1. Identifying the need for QA programs in x-ray facilities.
2. Identifying specific problems within facilities where QA can be effective.
3. Convincing the facility that when problems are found, there is a need for the establishment of a facility QA program.
4. Providing a method for confirming that any adopted QA programs within a facility have been effective.

Your obvious question is, when will such a manual be available. Originally the Task Force had hoped to have a draft of this manual at this meeting. However, we found it impossible to develop such a draft in the short period of time available from our first meeting in December. It is our intent to have the fourth meeting of this Task Force in the early fall, and following that meeting we hope that a draft document can be completed. We would anticipate that approximately 2 months will be needed for the typing and review of this draft document. We hope to be able to supply each program a copy of this final draft manual by the end of the calendar year.

I would like to publicly thank the members of this Task Force for the time and effort that they have given. I consider myself to be very fortunate in chairing a group of hard working and very talented people such as Murray Neuweg, Gene Fisher, Bob Craig, and Beattie DeBord. I would also certainly give my thanks to our Federal resources, DeVaughn Nelson, and, in particular, Dick Gross and Charlie Showalter.

TASK FORCE NO. 15

MAMMOGRAPHY

Henry J. Bicehouse, Chairman - Pennsylvania

For several years, a national debate has continued concerning the benefits and risks associated with the use of mammography. This debate continues with such issues as the screening of asymptomatic women under 50 years of age, selection of appropriate equipment and technique factors including image receptor selection, the measurement and reporting of the dose to breast tissue, the optimization of the parameters contributing to diagnostic quality in mammographic examinations, and the need for a conclusive demonstration that present day mammography is of benefit in routine screening of women over 50 years of age.

The Task Force believes that these controversies should be resolved on a national level by the consensus of all parties involved. However, regardless of their outcomes, the Task Force members recommend that whenever a mammographic examination is prescribed, it should be conducted at the lowest exposure for the given image receptor system that is consistent with diagnostic quality.

Task Force No. 15, Mammography, was charged with three tasks by the Healing Arts Council of the Conference in the fall of 1976:

1. to identify aspects of mammography that require guidelines and criteria for effective radiation protection or require further investigation;

2. to assist in the evaluation of the mammography quality assurance program effectiveness and to participate in its further development; and

3. to provide input into Federal programs relating to mammography.

The task force discussed most of the controversial issues surrounding mammography in the light of the first assigned task. The Task Force concluded that effective guidelines and/or criteria could not be formulated at this time. However, a delineation of the issues was attempted and is summarized below:

1. National agreement is needed in the area of patient selection criteria especially in screening programs involving asymptomatic women. These selection criteria should have a basis in the assessment of the risk/benefit ratio and should consider the appropriateness of the examination in the view of the patient and her doctor.

2. Effective guidelines are needed in the design, manufacture, and selection of x-ray equipment and image receptor systems.

3. There is little standardization and some misuse in the way that mammography doses and exposures are reported and discussed by physicists, radiologists, and patients.

4. Facilities conducting mammography need an effective quality assurance program to insure consistency in diagnostic quality.

BENT

In meeting its second and third tasks as assigned by the Conference, the Task Force has reviewed the Mammography Quality Assurance Program. This program is known as "Breast Exposure: National Trends" or BENT. The Bureau of Radiological Health developed this program in cooperation with the Radiation Control Programs in the District of Columbia, Pennsylvania, Minnesota, Massachusetts, and New Hampshire.

BENT provides the State with a method to estimate mammographic exposure in its facilities and enables the State to identify those with apparent quality assurance problems. Although BENT is not a substitute for a routine facility-based quality assurance and exposure monitoring program, it does provide information on the performance of the mammographic system as a basis for possible improvements.

The Task Force has reviewed the results of the BENT pilot studies and has concluded that these studies demonstrate:

1. individual radiologists and physicians have been satisfied with images produced with direct exposure film, vacuum-packed film/screen systems and xerodiography;

2. BENT pilot study exposures have ranged from 0.25R* to 16.6R* for all image receptor systems but the mean exposure for all image receptor systems was 1.5R*; and

3. followup surveys in many facilities with apparently high or unusually low exposures for the type of image receptor system used demonstrated correctable problems.

* Exposure-free in air at the skin entrance point for a single craniocaudal view of a "medium-density, medium-sized" breast

BENT currently reports exposure (R) free-in-air at the skin entrance site from a single craniocaudal view of a "medium-density, medium-sized" breast. The task force feels that it is appropriate for a State participating in BENT to report exposure (R) free-in-air; however, it also recognizes the need to relate measurement of exposure to other units of dose and exposure currently being utilized. For example, the Regional Centers for Radiological Physics, which monitor the exposures at the 27 screening centers for breast cancer, report their results as exposure but correct the results for back-scatter, which BENT does not. Others have reported rad and even rem doses. As pointed out earlier in the issues section, this has led to confusion. Further investigation and consensus is needed to standardize the intercomparison of the various units being reported.

BENT followup surveys conducted in the pilot States have also uncovered some additional controversial areas:

1. Additional information is needed on the routine use of "hotlights" in place of standard illumination viewboxes for reading films produced with vacuum-packed film/screen systems. This procedure is used with higher than normal density films and results in higher patient exposures. As a method for recovering needed diagnostic information from an otherwise overexposed film without additional exposure to the patient, the practice has merit. However, as a routine procedure for most mammograms as apparently required by some radiologists, this procedure produces exposure levels 2 to 8 times those experienced with normal density film reading procedures.

2. Extensive use of automatic exposure controlled x-ray units in mammography exists in several states. These units and their associated exposure cannot be properly evaluated with existing BENT dosimetry mailouts and present measurement problems during followup surveys. A method of estimating exposure from these units is needed. BENT pilot studies have demonstrated, in some cases, non-reproducible

exposure measurements with the same test phantom. The clinical significance of density differences noted on test films is unknown.

3. During one State pilot study, several facilities were found to be using image receptor systems which the manufacturer does not recommend for mammography. These atypical image receptors include conventional film/screen systems. The value of these image receptor systems in producing images of diagnostic quality in mammography is questionable because of increased mottle, artifacts, and so forth apparent on test films.

QUALITY ASSURANCE

BENT has demonstrated that Quality Assurance (QA) problems encountered in mammography are similar to QA problems encountered in general diagnostic radiology. Any QA program for general diagnostic radiology would apply to mammography.

ACTIVITIES OF THE TASK FORCE

To meet the assigned responsibilities, the Task Force met two times. Prior to the first Task Force meeting, the chairman attended the November 1976 meeting of the FDA's Regional Radiological Health Representative to hear the presentation of the Bureau of Radiological Health's mammography quality assurance program. At the December 14 - 15, 1976, meeting of the Task Force, staff members from the Bureau presented the program to the Task Force.

The Task Force met in Madison, Wisconsin on March 22-23, 1977. This site was chosen to allow the Task Force members to attend the Symposium on the Physics of Mammography sponsored by the Midwest Center for Radiological Physics on March 24-25, 1977. This symposium provided an overall view of the physics involved in mammography, the characteristics of mammographic equipment and image receptor systems, mammographic dosimetry, mammographic phantoms and new developments in mammographic imaging systems and physical measurements.

PLANS OF THE TASK FORCE

For its second year, the Task Force expects to continue to review and evaluate the BENT program. The Task Force will monitor and review the continuing national debate on the issues of mammography. The Task Force intends to integrate its activities with those of Task Force No. 14, on Quality Assurance to provide the Conference with recommendations for a quality assurance program specific to mammography.

TASK FORCE NO. 16

RADIATION MEASUREMENTS

Marshall Parrott, Chairman - Oregon

The Radiation Measurements Task Force was originally instituted by the National Bureau of Standards in a meeting in October 1975, in Gaithersburg. That Task Force has met now on seven occasions. A preliminary report was given to the Conference in Springfield last year.

1. There was unanimous agreement of the need for more direct National Bureau of Standards assistance to the States in the area of physical standards and measurement systems for radioactive materials and ionizing radiation. In particular, the National Bureau of Standards should develop a mobile calibration laboratory to assist the States in both quality assurance and training. Much of this information came from the original data that we asked each of you for, and we will be doing this again. However, it will be on a person-to-person basis and some of us will attempt to visit you personally.

2. The National Bureau of Standards should provide more standard reference sources directly to the State at little or no cost. Specific items that are needed will be determined and recommended in a future report.

3. The National Bureau of Standards should review and approve all Federal guidelines, standards, and regulations that require radiation measurements prior to the promulgation of such guidelines, standards, and regulations to assure that such radiation measurements are both technically feasible and practically attainable. I think Dr. Maxey pointed that out rather succintly.

4. The National Bureau of Standards should coordinate the development of model sampling procedures, chemical separation procedures, and analytical measurement methods for a variety of environmental radiocontaminants which could be used by all State, Federal, and private laboratories to assure consistency in the quality of measurement.

5. The National Bureau of Standards, in cooperation with EPA should be designated as a Federal agency responsible for coordinating efforts among the Federal and State agencies to immediately develop a uniform data reporting system so that present environmental data that are being generated throughout the country can be used and evaluated in terms of possible exposure to population.

6. The National Bureau of Standards should design a model calibration facility and recommend procedures for calibration of field ionizing radiation survey instruments and monitoring systems.

7. There is need for additional training for all State personnel involved in ionizing radiation measurement. Training programs should be sponsored and supported by all Federal agencies involved in ionizing radiation measurement. It is recommended that the Conference of Radiation Control Program Directors establish a task force on training that would, as part of their efforts, coordinate the training activities sponsored by Federal agencies.

8. The National Bureau of Standards should begin to work with specific States to resolve specific measurement problems that could be applicable to the remaining States. Such areas may include the design and operation of a State calibration facility, calibration of specific instruments for specific types of measuring problems, and so forth.

9. The present Environmental Protection Agency Radioactivity Laboratory intercomparison study program provides a cross check on individual laboratories. That program has been very successful in identifying specific problems; however, there is presently no followup program to provide assistance to those laboratories that a cross-check program identifies as having some problems. The task force recommends that the Environmental Protection Agency and the Nuclear Regulatory Commission, the Energy Research and Development Administration, and the National Bureau of Standards cooperate in resolving this issue.

10. The Task Force was unable, because of restrictions in time, to adequately address all of the problems of radiation measurement. For that reason, it restricted its area of concern to ionizing radiation measurements only. In the field of ionizing radiation measurements, the Task Force was only able to scratch the surface of the problem. It is believed that a more in depth analysis would be appropriate and may alter the above recommendations.

Therefore, the National Bureau of Standards should continue to sponsor the Task Force on Radiation Measurements in a manner suitable to both the National Bureau of Standards and the Conference of Radiation Control Program Directors. The National Bureau of Standards has provided the Conference with the preliminary proposal for continued support of this Task Force, and has asked the goal in the coming year of that Task Force to be to obtain an in-depth understanding of present accuracy requirements for radiation measurement systems and suggest mechanisms for achieving desired accuracy.

TASK FORCE NO. 17

PERSONNEL DOSIMETRY

Larry Lloyd, Chairman - Montana

The Conference, at its 1973 meeting in Portland, sponsored a workshop on personnel dosimetry. The workshop concluded that "Users of personnel dosimetry devices have little assurance that reported dose assessments are reliable." The workshop also concluded that the Conference could be used as a vehicle to assemble concerned Federal agencies and to coordinate the development of a reliability testing program for suppliers of personnel dosimetry services.

Following the Portland meeting, the Conference Executive Committee established a Task Force on Personnel Dosimetry. The Task Force was composed of three Conference members: Larry Lloyd, Chairman, Montana; Hal Stocks, Indiana; and William Spell, Louisiana. The Task Force secured liaison members from the U.S. Food and Drug Administration/Bureau of Radiological Health; the U.S. Environmental Protection Agency; the U.S. Atomic Energy Commission (now the Nuclear Regulatory Commission and the Energy Research and Development Administration); and the National Bureau of Standards.

The goal of the Task Force was to coordinate efforts to develop a reliability assurance program for suppliers of personnel dosimetry services. To accomplish this goal, the Task Force met with Federal liaison personnel in September 1973, March 1974, and May 1975, to discuss mechanisms for the development of the reliability assurance program. In addition, Task Force members met with National Sanitation Foundation personnel at Ann Arbor, Michigan, during December 1973, and with Battelle Northwest staff at Richland, Washington, during February 1974, to discuss reliability assurance programs for suppliers of dosimetry services.

During 1974, an Ad Hoc Interagency Technical Task Force was formed to facilitate coordination between the various interested Federal agencies in developing a testing program for personnel dosimetry services. Agencies represented on this Task Force are FDA/BRH, NBS, NRC, ERDA, AND NIOSH. This Task Force has been effective in maintaining interest, support, and direction in the development of the program.

In February 1974, the Bureau of Radiological Health transferred $16,000 by Interagency Agreement to the National Bureau of Standards for the purpose of developing a unified set of methods and criteria for testing the performance of suppliers of film and thermoluminescent personnel dosimeters and for conducting a baseline performance study of commercial suppliers of personnel dosimeters. The National Bureau of Standards subsequently contracted with Battelle Northwest to conduct the baseline study. Results of this baseline study indicated that the state-of-the-art had not changed significantly over the past 10 years for film dosimeters. For example, when results were compared to a previous study performed by Battelle in 1967, the pass-fail rate was about the same when identical criteria were used. The overall quality of TLD results was the same as film for most radiation types.

The 1974-75 Battelle study pointed out shortcomings in the application of current and proposed standards for the testing of personnel dosimeters. Standards were based on the accuracies and performance capabilities of the dosimeters rather than on the accuracies and performances required or dictated by health physics considerations.

In July 1975, the Bureau of Radiological Health transferred by Interagency Agreement an additional $25,000 to the National Bureau of Standards for the development of minimum performance standards for suppliers of personnel monitoring services.

Doctor Margarete Ehrlich of the National Bureau of Standards subsequently developed a preliminary draft of new standards for the testing of personnel dosimetry services. This draft was sent to the Health Physics Society Standards Committee. The Standards Committee referred the draft to Workgroup No. 15 chaired by Doctor Ehrlich, for the development of a proposed standard "Criteria for Testing Personnel Dosimetry Performance." A preliminary draft of the proposed standard was completed by Workgroup No. 15 and distributed for comment in November 1976. This draft was then forwarded to the American National Standards Institute (ANSI) N.13 Committee from where it was again sent out for comment. The ANSI comments were returned to the Health Physics Society Workgroup No.15 where the draft standard is being revised with a deadline of June 20, 1977, when it will be sent concurrently to the Health Physics Society Standards Committee and to the ANSI N.13 Committee. It is anticipated that this document will become an approved ANSI standard in the fall of 1977.

A major step toward the development of a personnel dosimetry testing program was realized in 1976 by the NRC commitment to a change in the 10 CFR 20 regulations to require licensees to use a dosimetry service participating in the testing program.

The Bureau of Radiological Health, the Nuclear Regulatory Commission, and the Energy Research and Development Administration sponsored a public meeting on the performance testing of personnel dosimetry in Washington, D.C. on November 30 and December 1, 1976. Larry Lloyd represented the Conference and delivered a prepared statement at this meeting. Approximately 110 representatives from varying interests attended this meeting. Representatives from the following were noted:

1. Commercial personnel dosimetry suppliers.
2. Private personnel dosimetry suppliers.
3. Federal regulatory agencies.
4. Testing laboratories (National Sanitation Foundation & Battelle Northwest).
5. ERDA contractors.
6. National Bureau of Standards.
7. Conference of Radiation Control Program Directors, Inc.

Probably the most important point of this meeting was the fact that there was no opposition to the development of a personnel dosimetry testing program. All meeting participants agreed on the need and urged development of the program.

Other highlights of the meeting were as follows:

1. The NRC announced intention to issue a Request for Proposal (RFP) for a 1-year test of the Health Physics Society proposed standard and their financial support of the special study to be performed by the selected laboratory.
2. ERDA confirmed their commitment to use the tested standard for its contractors and will cooperate in the test during 1977.
3. The Conference of Radiation Control Program Directors reaffirmed interest in the program emphasizing:
   a. Calibration sources should be traceable to NBS.
   b. The standard must apply to all energy ranges of photon radiation.

4. Several attendees recommended the establishment of an "overview" group to supervise the test program and to insure scientific base for conduct as well as fair treatment of processors. It was recommended that this group should include processor and user representatives as well as Federal representatives.

It was generally agreed that:

(a) BRH and ERDA must be active participants with NRC in the program and that NBS must be involved in the testing.

(b) The testing laboratory(ies) must have a specific responsibility to one or more Federal agencies and should become self-supporting from fees charged to processors.

On April 21, 1977, the NRC issued a Request for Proposals (RFP) on Performance Testing of Personnel Dosimetry Services. The testing will be based on the current draft of the proposed Health Physics Society Standards Committee (HPSSC) standard "Criteria for Testing Personnel Dosimetry Performance." This work proposes to conduct pilot tests for dosimetry processors prior to the amendment of 10 CFR 20. The objectives of this work are:

(a) to give processors an opportunity to correct any problems that are uncovered;

(b) to develop operational and administrative procedures to be used later by a permanent testing laboratory; and

(c) to determine whether the proposed HPSSC standard provides an adequate and practical test of dosimetry performance.

A preproposal conference was held on May 3, 1977, with prospective bidders to answer any questions they might have regarding the proposal. Four prospective bidders attended: Battelle Northwest, University of Michigan, University of Virginia, and Radiation Measurements, Inc. of Middleton, Wisconsin.

The NRC is currently predicting that they will publish notice of proposed rule change to require licensees to use tested dosimetry services in January or February 1978. The time schedule for the effective rule change will probably be about June 1980.

An Interagency Policy Committee on Personnel-Radiation Monitoring was established in early 1977. The general purpose of the Policy Committee is to ensure that rules, procedures, and so forth, issued by the various Federal agencies involved in personnel-monitoring control will be consistent. This will tend to reduce the impact on the user following changes in regulations and will enable the Federal Government to present a unified program to the states.

The Policy Committee Chairman, Doctor James Leiss, NBS, invited the Conference to provide a state consultant to the Policy Committee. Chairman Jerry Parker asked Larry Lloyd to serve with that Committee.

The Interagency Technical Task Force will continue to take care of technical matters, while the Policy Committee--as its name implies--will be concerned primarily with matters of policy.

At this time it appears that the development of the Conference-envisioned personnel dosimetry testing program is progressing satisfactorily and that the testing program will probably become operational in 1980.

Recommendations:

1. The Conference should continue to monitor and to support the development of the personnel testing program.
2. A one-member task force on personnel dosimetry should be maintained to monitor program development and to act as the Conference consultant to the Interagency Policy Committee on Personnel-Radiation Monitoring.

REPORT OF THE WORKING GROUP ON THE LEAK TESTING OF THE GENERAL LICENSE DEVICES OF 10 CFR 31.5

Albert J. Hazle, **Chairman** - Colorado
Aubrey Godwin - Alabama
Philip Brunner - Illinois
Dayne H. Brown - North Carolina
Martin C. Wukasch - Texas

This Task Force was established following the working group report at the Eighth Annual Conference in Springfield, Illinois.

Subsequently, 52 jurisdictions were polled as to available data concerning violations of the general license conditions of 10 CFR 31.5 or its equivalent. A draft report was prepared and submitted to the Task Force membership and the NRC for review prior to submission to the Conference Executive Committee. In a letter from the NRC, regarding the draft report, they requested that the Task Force gather some additional data prior to finalizing the report. Currently, Darrel McDaniel of our staff is contacting various States regarding the NRC comments with little success.

I hereby request that my letter of March 7, 1977, with its enclosure and its attachments, along with the NRC response be included in the proceedings of this meeting thereby demonstrating the need for data and increased regulatory effort to remedy the situation.

ENCLOSURE A

TECHNICAL AND EDITORIAL COMMENTS

1. Page 1, Category 5 should read: "...maintain installation survey records."
2. Page 1, 4th line from bottom. We suggest spelling out both ACASPA and OSHA.
3. Page 3 of the table of violations, footnote 1. The footnote seems to imply that the five categories are failures to comply with safety or regulatory reuqirements. The General License of 10 CFR 31.5 does not require the general licensee "to report receiving a device," does not specify who are authorized users; and, except for 10 CFR 20.402 and 20.403, exempts the general licensee from the requirements of 10 CFR 19 and 20. Accordingly, failures to maintain records other than specified in 10 CFR 31.5 and to post radiation areas, are not violations. The report should, therefore, provide an explanation of why these findings are considered to be "administrative problems."

CATEGORIES OF ITEMS OF NONCOMPLIANCE

The Commission and representatives of the nuclear industry have recognized that the significance of items of noncompliance with AEC requirements varies in the potential for affecting the health and safety of the public, the common defense and security, and the environment. The Commission considers that it is desirable to include in Notices of Violation an indication of the significance of each item of noncompliance cited. As a means of categorizing the items of noncompliance into an order of importance which will express their relative significance, the Commission has established three categories of items of noncompliance as follows.

VIOLATION

A violation is an item of noncompliance of the type listed below, or an item of noncompliance (1) which has caused, contributed to or aggravated an incident of the type listed below, or (2) which has a substantial potential for causing, contributing to or aggravating such an incident or occurrence; e.g., a situation where the preventive capability or controls were removed or otherwise not employed and created a substantial potential for an incident or occurrence with actual or potential consequences of the type listed below:

(a) Exposure of an individual in excess of the radiation dose specified in 10 CFR 20.403(b) or exposure of a group of individuals resulting in each individual receiving a radiation dose for the group exceeding 25 man-rems.

(b) Radiation levels in unrestricted areas which exceed 50 times the regulatory limits.

(c) Release of radioactive materials in amounts which exceed specified limits, or concentrations of radioactive materials in effluents which exceed 50 times the regulatory limits.

(d) Fabrication, or contruction, testing, or operation of a Seismic Category I systemor structure in such a manner that the safety function or integrity is lost.

(e) Failure to function when required to perform the safety function or loss of integrity of a Seismic Category I system, or structure; or other component, system, or structure with a safety or consequences limiting function.

(f) Exceeding a safety limit as defined in technical specifications associated with facility licenses.

(g) Industrial sabotage of utilization or fuel facilities.

(h) Radiation or contamination levels in excess of limits on packages or loss of confinement of radioactive materials in packages offered for shipment on a common carrier.

(i) Diversion or theft of plutonium, uranium-233, or uranium enriched in the isotope U-235.

(j) A breakdown in management or procedural controls as evidenced by items of noncompliance in several areas of the QA criteria and license requirements.

(k) Other similar items of noncompliance having actual or potential consequences of the same magnitude.

Failure to report the above items as required constitutes a violation of the same importance level.

INFRACTIONS

An infraction is an item of noncompliance of the type listed below, or an item of noncompliance (1) which resulted in a reduction of preventive capability below requirements but redundant controls precluded an item of noncompliance of the violation category; or (2) which caused, contributed to, or aggravated an incident of the type listed below, or (3) which has a substantial potential for causing, contributing to or aggravating such an incident or occurrence; e.g., the preventive capability or controls were removed or otherwise not employed and there was substantial potential for an accident or occurrence with actual or potential consequences of the type listed below:

(a) Exposure of an individual or groups of individuals to radiation in excess of permissible limits but less than the values in 10 CFR 20.403.

(b) Release of radioactive materials in concentrations or rates which exceed permissible limits but in amounts less than permissible limits.

(c) Failure to function or loss of integrity of a Seismic Category I system or structure, or other component, system, or structure with safety or consequences limiting function during test; or failure to meet surveillance frequencies.

(d) Fabrication, or construction, testing, or operation of a Seismic Category I system or structure in such a manner that the safety function or integrity is impaired.

(e) Exceeding limiting conditions for operation (unable to read hard copy)

(f) Inadequate management or procedural controls.

(g) Safety system settings less conservative than limiting safety system settings.

(h) A quantity of SNM unaccounted for, which exceeds permissible limits.

(i) Exceeding limits or limiting conditions for operation in licenses, technical specifications, guides, codes, or standards which are imposed for the purpose of minimizing adverse environmental impact.

(j) Other similar items of noncompliance having actual or potential consequences of the same magnitude.

Failure to report the above items as required constitutes an item of noncompliance of the same category.

DEFICIENCY

A deficiency is an item of noncompliance in which the threat to the health, safety, or interest of the public or the common defense and security is remote; and no undue expenditure of time or resources to implement corrective action is required; and deficiencies include such items as noncompliance with records, posting, or labeling requirements which are not serious enough to amount to infractions.

Failure to report deficiencies as required constitutes an item of noncompliance of the same category.

TASK FORCE ON 10 CFR 31.5

Subsequent to the Working Group Report at the Eighth Annual Conference Springfield, Illinois), a Task Force was established to review the General License of 10 CFR 31.5 concept and its present regulatory status.

To that end, 52 jurisdictions were polled as to any data that has been gathered concerning violations of the general license conditions of 10 CFR 31.5 or its equivalent. Letters were sent to the jurisdictions October 27, 1976, and January 3, 1977, resulting in 39 agencies responding. There was no response to the request for information from 13 radiological health programs.

Twenty-four agencies of the 39 reporting, stated they had no data available on the subject. Four additional State agencies responded with general comments regarding the problems they have encountered with generally licensed devices.

Information from the 15 agencies providing data were categorized into 8 areas of interest.

1) Source malfunction
2) Physical damage to the device.
3) Lost device (device sold in State but agency cannot locate it).
4) Failure of licensee to check on-off mechanism.
5) Failure of licensee to maintain survey records.
6) Failure of licensee to leak test and/or maintain records.
7) Failure to maintain required labeling or posting.
8) Administrative problems (5 specific areas).

From the limited data available, 2 source malfunctions, 7 physical damage to the device, 11 "lost" devices, 8 instances of on-off mechanism check non-compliance, 6 instances of failure to maintain installation records, 40 instances of failure to perform leak tests and/or maintain leak test records, and 19 instances of labeling requirement non-compliance were identified. Twenty-two administrative problem areas were observed. It is unknown as to the total number of installation inspections that these violations encompassed.

Of the 25 Agreement States, 5 did not respond, 7 had no data available, and 13 provided information, indicating only about one-half of the Agreement States have any sort of a compliance program in the area of general licenses. Ohio and Virginia were the only non-Agreement States which provided information. Los Angeles and New York City reported no data available.

However, several other items were observable from the information derived. From the limited number of inspections of which the summary is representative, although such devices are under regulation, inspection priority is low. In some cases the inspections performed were accomplished due to the fact that the generally licensed devices were specifically licensed so that the licensee could perform the leak tests or relocate the devices. ACASPA under OSHA was involved with one generally licensed device inspection.

Due to the number of violations observed, general licensees have not met the minimum requirements of the regulations.

Because of the magnitude of radioactive material in certain devices authorized under 10 CFR 31.5 or its equivalent, the lack of data, particularly in State files, the Task Force requests that the U.S. Nuclear Regulatory Commission investigate its regulatory program under 10 CFR 31.5 from both a regulation and compliance standpoint so that the concerns of the Task Force, as expressed in the Working Group Report (1976), may be addressed.

Attached to this report are copies of:

1) Working Group Report (Springfield).
2) Parker Memorandum, October 15, 1976.
3) October 27, 1976 and January 3, 1977 letters.
4) Summary Listing of Data.

The Task Force wishes to express its appreciation to Darrel McDaniel, Colorado, for his efforts in reviewing the provided information and preparing the statistical summary.

Respectfully submitted,

Albert J. Hazle, Chairman, Colorado
Aubrey Godwin, Alabama
Philip Bruner, Illinois
Dayne H. Brown, North Carolina
Martin C. Waukasch, Texas

EIGHTH ANNUAL CONFERENCE
SPRINGFIELD, ILLINOIS

WORKING GROUP REPORT
ON THE
LEAK TESTING OF THE GENERAL LICENSE DEVICES
OF
10 CFR 31.5

As a result of the last NRC-Agreement States meeting, at which time North Carolina reported on the results of a limited survey of General License Devices under 10 CFR 31.5 equivalent, a meeting was requested by NRC to review the questions raised by the study.

The study in question was completed in the summer of 1975 and was based on North Carolina's current regulations. Their regulations as well as those of other Agreement States have not been amended to include the revised portions of the NRC equivalent which were amended in January 1975. The main difference between the current Agreement States and the NRC regulations is that a General Licensee is authorized to do leak testing without the requirement of being knowledgeable on the salient features of radiation protection.

Based on rather limited information it has been identified that:

1) The general licensee is not knowledgeable of the requirements of the general license under which he possesses the material.

2) In many cases the general licensee is unaware that he, in fact, does possess radioactive material or the magnitude of his posession.

3) The requirements of the general license are not being met:

   a) Leak testing is not being done.
   b) Required labeling is being obliterated as a result of faulty environments and plant maintenance operations.

4) Exposure in excess of applicable standards are difficult to document.

A definite positive approach to the total regulatory approach to the 31.5 General License Device is necessary. The basics for a fully implemented program exist; however, present priorities preclude a concerted effort in this specific area of interest by both Federal and State agencies. Several suggestions were proposed to improve the situation:

> Place the 31.5 general licensee on an inspection priority to acquire more data on the magnitude of the situation and correct those deficiencies found to exist in the field. This would apply to both Federal and State agencies.
>
> Require the manufacture and distribute specific licensee to evaluate the circumstances of the use or proposed use of their devices and to limit or preclude such use if it is deemed appropriate in the best interest of health, safety and regulatory control, and to preclude misuse of their device.
>
> Reevaluate the philosophy supporting the concept of the general license as contained in 10 CFR 31.5. This would include the original consideration when the general license was initially implemented and the current regulatory practices. Under this concept possibilities exist of classifying such devices by several schemes and placing the appropriate devices in an exempt or a specific license status, and elimination of the general license.

A license fee or leasing requirement may indirectly correct the item currently of concern.

While the initial topic of discussion was the necessity of leak testing of these devices, the meeting rapidly centered on the philosophy of the general license as contained in 10 CFR 31.5. It was agreed that little is actually known as to the magnitude of the situation and the impact to public health and safety. While the mechanisms for implementation of regulatory control presently exist at Federal and State level, little is being done to truly ascertain the efficacy of protection provided. This is not in the best interest of the general public, the general licensee, his employees or of the agencies charged with regulatory control.

An additional concern is the placement of requirements on such general licensees based on the regulations of other agencies (i.e., postal regulations). What jeopardy do we place the licensee and the radiation control agency in if this is not done and an incident does occur? The question of contributory negligence is raised.

Recommendations:

1) That the Conference establish a Task Force to review the General License of 10 CFR 31.5 concept and its present regulatory status. The Task Force membership should include representatives from Agreement and non-Agreement States having regulatory control over the manufacture and distribution of such generally licensed devices and the various office of the NRC.

2) That this Task Force report to the Conference its findings, and any recommended plan of action to correct the situation if such is deemed in the best interest of public health and safety.

This report has been prepared by the chairman of the meeting and is primarily his interpretation of the deliberations of the group.

Respectively submitted,

Albert J. Hazle, Meeting Chairman

I. Conference Representatives

Albert J. Hazle, Colorado, Current Agreement States Spokesman
Dayne H. Brown, North Carolina
Ed Bailey, Texas
Aubrey Godwin, Alabama
Maurice Neuweg, Illinois
Lynn Fitzrandolph, Arizona

II. Resource Agency Representative

Donovan Smith, SD/NRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION
Washington, D.C. 20555

Mar 30 1977

Ref: SA/JOL

Albert J. Hazle, Director
Occupational and Radiological
Health Division
Colorado Department of Health
4210 East 11th Avenue
Denver, Colorado 80220

Dear Al:

Thank you for the opportunity to review the draft report of the Task Force on General Licensing of 10 CFR 31.5. Our technical and editorial comments are enclosed (Enclosure A).

We suggest that the report address the following areas:

(1) The Task Force should assess the data for its effect upon the public health and safety. For example, 7 cases involving physical damage to the device are reported. Did any of these result in or threaten to cause overexposures of individuals, increases in radiation levels, breach of source containment, etc.? As you know, NRC regulatory practices recognizes that the significance of violations varies in the potential for affecting health and safety (Enclosure B). You may wish to characterize the data along similar lines. We do not believe the report should treat, as examples, a labelling violation on a unit otherwise in compliance as having the same safety significiance as damage to a device which resulted in a compromise of the source containment and overexposures of individuals.

(2) The Task Force should obtain additional information to enable gaining some perspective on the relative frequency of these violations and problems. We noted that the report states no data was available on the total number of inspections that the data encompasses. A total of 115 individual violations or problems were reported. How many facilities or devices were affected? Is some of the data repetitive (i.e. results of reinspections of the same licensee or device)? For the 15 agencies who provided data, can the number of licenses or devices under their jurisdiction be established?

We believe value and reception of the Task Force report will be enhanced if these suggestions are adopted.

I am concerned over the low-level of participation by the Agreement States. Twelve of these States either did not respond or reported no data was available. Inasmuch as this represents nearly half of the Agreement States, it may be appropriate to either reattempt to gain their participation or include a note in the report concerning the possible impact upon the validity of the data and conclusions.

/s/
G. Wayne Kerr, Assistant Director
for State Agreements Program
Office of State Programs

Enclosures:
As stated

SESSION: X-RAY DATA AND GUIDANCE

Moderator: *Lawrence J. McDonnell*, Wisconsin

RESULTS OF REPEATED NEXT SURVEYS IN THE STATE OF OKLAHOMA
Robert L. Craig, Radiation Protection Division, Oklahoma State Department of Health
David W. Johnson, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

POTENTIAL IMPACTS OF CONTROL PROGRAM EFFORTS ON GENETICALLY SIGNIFICANT DOSE (GSD) AND BONE MARROW DOSES
David W. Johnson, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

BREAST EXPOSURE: NATIONWIDE TRENDS - PROGRESS TO DATE
Ronald G. Jans and Thomas R. Ohlhaber, Bureau of Radiological Health, FDA

FEDERAL GUIDANCE FOR DIAGNOSTIC X RAYS
James E. Martin, Ph.D., Deputy Director, Criteria and Standards Division, Office of Radiation Programs, EPA

THE STATES' VIEW OF FEDERAL GUIDANCE REPORT NO. 9
David K. Lacker, Radiation Control Branch, Texas Department of Health Resources

SESSION: LOW-LEVEL RADIOACTIVE WASTE MANAGEMENT

Moderator: *William C. Horton*, Nevada

NRC TASK FORCE REPORT ON REVIEW OF THE FEDERAL/STATE PROGRAM FOR THE REGULATION OF COMMERCIAL LOW-LEVEL RADIOACTIVE WASTE BURIAL GROUNDS
William P. Bishop, Michael J. Bell, Kitty S. Dragonette, and John A. Adam
Waste Management Program, U.S. Nuclear Regulatory Commission

STATE EXPERIENCE WITH WASTE BURIAL SITES AND THEIR RESPONSE TO NRC'S TASK FORCE
Frederick S. Adair, Washington Energy Office, Representative to the Western Interstate Nuclear Board
Charles M. Hardin, Radiation Control Branch, Kentucky Department of Human Resources
Heyward G. Shealy, Bureau of Radiological Health, South Carolina Department of Health, Health and Environmental Control
James A. Blackburn, Radioactive Materials Licensing, Illinois Department of Public Health

SESSION: SO YOU ARE GOING TO COURT

Moderator: *Donald E. Van Farowe*, Michigan

EVIDENCE PREPARATION
Raymond Malecko, Food and Drug Administration

LEGAL ASPECTS OF A REGULATORY INSPECTION AND ENFORCEMENT PROGRAM
Allen D. Johnson, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission

PREPARING TO ACT AS A WITNESS
Richard A. Lane, Bureau of Occupational and Institutional Hygiene, Department of Environmental Services, District of Columbia

SESSION: TECHNICAL POTPOURRI I

Moderator: *J. Ellis Simmons*, Nebraska

USE OF OBSTETRIC ULTRASOUND IN U.S. HOSPITALS, 1974
Paul L. Roney and Peggy Hamilton, Bureau of Radiological Health, FDA

OVERVIEW OF NONIONIZING RADIATION PROGRAMS OF NIOSH
G.E. Moss, National Institute of Occupational Safety and Health

PROBLEMS AT INACTIVE OR ABANDONED FUEL CYCLE FACILITY SITES
W.T. Crow, Nuclear Regulatory Commission

RESULTS OF REPEATED NEXT SURVEYS IN THE STATE OF OKLAHOMA

Robert L. Craig
Radiation Protection Division
Oklahoma State Department of Health

and

David W. Johnson
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

The State of Oklahoma became a participant in the Nationwide Evaluation of X-Ray Trends (NEXT) during the last quarter of 1972.

When NEXT was first begun, we recognized that it had a tremendous potential for giving us vital information necessary for the management of our diagnostic x-ray program. As a result we committed ourselves to it very strongly. In the first stages we selected a random sample of our facilities to receive NEXT surveys. We quickly realized that collecting data in this fashion, while it would give us some statistics within a year, was very costly in terms of travel and personnel time because the facilities were also randomly distributed geographically.

In the fall of 1973, we made the decision to abandon the random selection of facilities and, instead, to perform NEXT surveys during all of our inspections. We realized that this would cost us some time before adequate statistics would become available but we considered that the extra time would be well spent in developing a much larger data base and enabling us to schedule inspections in a much more rational and economically justifiable manner. This decision has been shown to be a wise one because we have been able to inspect all of the diagnostic x-ray facilities in the State since then (as a matter of fact, I received a call at the Springfield meeting telling me that the State had been finished).

As time goes on, the number of repeat surveys will increase rapidly since almost every inspection we make will be on a machine that has already been surveyed.

Since we became involved in NEXT, surveys that include more than 4500 projections have been done and submitted to the Bureau of Radiological Health in Rockville, Maryland for processing. During this period of about 4-1/2 years, all medical and dental x-ray facilities in the State have been surveyed at least once, and some two or three times. Figure 1 shows the trend in mean exposure at skin entrance (ESE) for three exams; chest, lumbo-sacral spine, and dental bitewing. From this graph no clear trend is evident. This is partially because our method of selecting facilities for survey has a rotation period of about 2 years.

Today we will look at the data from a slightly different viewpoint. Approximately 800 of the NEXT surveys in Oklahoma have been performed on the same tube for the same type of projection as at least one previous NEXT survey. As such, these surveys do not necessarily represent a random sample of facilities in the State, but do represent a sizeable number of machines for which we have measurements at two points in time. These surveys are separated by at least 1 year and in some cases 2 or 3 years.

Table 1 shows the distribution by type of exam/projection for the repeat surveys we had on the NEXT master file in mid-May when we began developing the statistics for this paper.

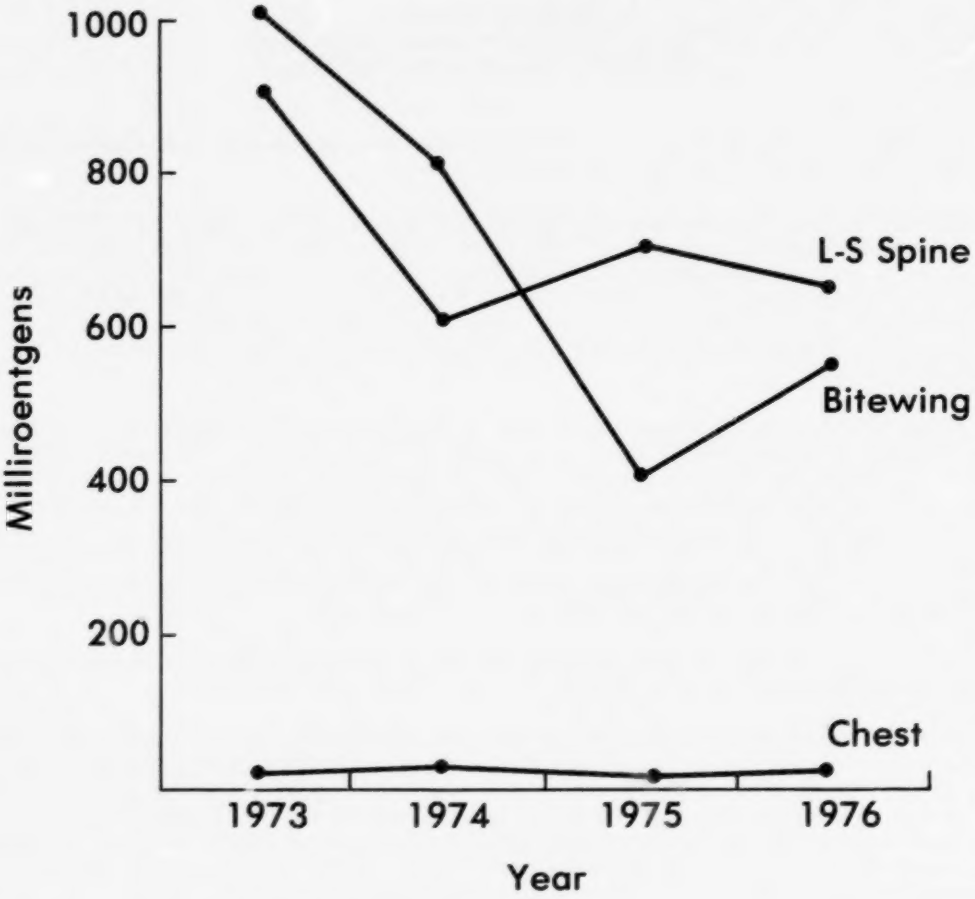


Figure 1. Mean exposure at skin entrance, Oklahoma, 1973 - 1976.

Table 1. Distribution of repeat surveys by type of examination

Exam	Number	Percent
Chest, PA	192	24.7
Skull	6	0.8
Abdomen	29	3.7
Retrograde Pyel.	6	0.8
Thoracic Spine	2	0.3
Cervical Spine	10	1.3
L-S Spine	39	5.0
Full Spine	7	0.9
D. Bitewing	256	32.9
D. Periapical	224	28.8
D. Cephalometric	2	0.3

Only the chest, abdomen, lumbo-sacral spine, dental bitewing, and dental periapical examinations have been repeated enough times to produce statistics such that we can place much confidence in the averages generated. For this reason, these are the only exams for which any comparisons will be made.

Table 2 shows the distribution of x-ray facilities in Oklahoma.

Table 2. Types of x-ray facilities in Oklahoma

Type	Number	Percent
MD	319	14.9
DO	107	5.0
DDS	909	42.5
DSC	49	2.3
DVM	128	6.0
DC	190	8.9
Clinic	262	12.3
Hospital	174	8.1
Total	2139	100.0

When we first began to compare the results of the repeat surveys with the those of the first surveys we were startled, to say the least. This first comparison is shown in Table 3 and, while bitewings and periapicals showed a slight decrease, all of the rest of the exams (including those not shown in table 3) showed increases. Although we had not expected to see much change in ESE at this time because we were concentrating primarily on machine-oriented factors that do not affect ESE to any large degree, we certainly had not anticipated an increase (dramatic in some cases). In attempting to explain this apparent increase, we discovered that we had been expecting NEXT to apply the instrument correction factors to the exposure measurements while the computer was processing the data. This assumption was wrong and no corrections had been made. This is particularly important since in the early days of NEXT we had used the Victoreen 666 and 2.5R ion chambers and later had been using the MDH Model 1015 almost exclusively. Some of our earlier instrumentation had been reading as much as 20 percent low.

Once this was recognized, we dug into the NEXT files and got some average correction factors for each of the types of instrumentation used. We applied these correction factors to the data and the results shown in table 4 were more in line with what one would expect the situation to be, about 20-percent decrease in the ESE for bitewings and periapicals and essentially no change for the other exams. I will discuss the apparent increase for the abdomen later.

Table 3. Comparison of exposure at skin entrance (in milliroentgens, free-in-air)

Exam	First survey	Repeat survey	Ratio Repeat:First
Chest, PA	22	23	1.05
Abdomen	560	689	1.23
L-S Spine	720	851	1.18
D. Bitewing	661	633	0.96
D. Periapical	637	606	0.91

Table 4. Comparison of exposure at skin entrance adjusted for instrument response (in milliroentgens, free-in-air)(in milliroentgens, free-in-air)

Exam	First survey	Repeat survey	Ratio Repeat:First
Chest, PA	25	23	0.92
Abdomen	651	710	1.09
L-S Spine	837	846	1.01
D. Bitewing	763	642	0.84
D. Periapical	738	608	0.82

We also discovered another anomaly in this comparison. Table 5 shows that the half-value layers (HVL) found during the repeat surveys were smaller than were found during the first survey. This was another situation which experience led us to believe was not real. Since the response of all instruments is energy dependent to a greater or lesser degree, we applied HVL correction factors for the different types of instruments that we had used. The correction factors used are those that NEXT will begin using with the new dose model when it is implemented. Once this was done, the HVL's as shown in table 6 were almost identical with the exceptions of slight increases for chest and the dental exams and a decrease for abdomens. The data now make sense because lack of adequate filtration is considered to be a serious violation of Oklahoma's regulations and is subject to vigorous action to achieve compliance. The resolution of this anomaly has cleared up some very serious questions in the minds of the Oklahoma staff regarding the reasons we were apparently finding less filtration at the time of the second survey when we knew that significant numbers of machines had added filtration.

The apparent increase in ESE and decrease in HVL for the abdomen illustrates the need for a large data base from which to derive statistics. In comparing these apparent differences with their respective standard deviations, the differences are not statistically significant and the results of the first and repeat surveys are essentially the same.

Table 5. Comparison of half-value layers (mm Al eq.)

Exam	First survey	Repeat survey	Ratio Repeat:First
Chest	2.95	2.67	0.91
Abdomen	3.45	2.84	0.82
L-S Spine	3.09	2.73	0.88
D. Bitewing	2.30	2.17	0.94
D. Periapical	2.27	2.14	0.91

Table 6. Comparison of half-value layers adjusted for instrument response (mm Al eq.)

Exam	First survey	Repeat survey	Ratio Repeat:First
Chest, PA	2.42	2.46	1.02
Abdomen	2.82	2.59	0.92
L-S Spine	2.53	2.51	0.99
D. Bitewing	1.79	1.90	1.06
D. Periapical	1.74	1.89	1.09

Table 7 shows the mean ratio of beam area to film area of rectangular beams for first and repeat surveys while table 8 shows the same information for circular beams. This comparison showed what we had expected, that we had achieved some reduction in radiation exposure through improvement in collimation. Nevertheless, there are some anomalies in these data also.

Table 7. Comparison of beam area to film area for rectangular beams

Exam	First survey	Repeat survey
Chest, PA	2.33	1.38
Abdomen	1.11	1.11
L-S Spine	1.49	1.13
D. Bitewing	1.94	1.71
D. Periapical	*	*

* No rectangular collimation for this exam

Table 8. Comparison of beam area to film area for circular beams

Exam	First survey	Repeat survey
Chest, PA	4.20	3.09
Abdomen	1.37	1.43
L-S Spine	1.89	1.93
D. Bitewing	2.78	2.64
D. Periapical	2.73	2.63

The use of direct print paper to measure the beam size has also allowed us to visualize the beam shape and, unless you have seen some of them, it is difficult to believe the shape of some of these beams. They range from good rectangles and circles to straight sided figures with no two sides parallel and mashed ovals to half moons and other shapes that cannot be described. As a result some of the uncollimated beams were coded as rectangular simply because they could not be called circular. These undescribable beams contribute to high ratios of beam area to film area for machines with rectangular collimators. Of the 192 machines for which a chest projection was done, 46 tubes (24 percent) used circular cones or had no collimator at all. Twenty-four of these machines had added improved collimation (changed from no collimation to a circular cone or changed from a circular cone to a rectangular collimator) prior to the repeat survey. In addition, a few practitioners decided to stop taking x-rays rather than bring the machines into compliance with our regulations.

This leads me to mention a problem of which I am sure you wish you were not quite so aware. At this time we have about 20 facilities that are in violation of our State regulations, and have been for up to 2 years, because of the extreme scarcity of collimating devices that are either simply not legally available at any price or, if they are available, do not cost more than the machine on which they are to be installed is worth. I am sure that you all know the position of the Oklahoma staff regarding the positive beam limitation requirement in the Federal x-ray standard because we have stated it loudly and frequently. The possibility of alleviating this collimator crisis is the reason we are so pleased recently to see that FDA and BRH are reconsidering the PBL requirement.

An examination of the type of regulations that we in Oklahoma, and most of the other States, have shows that they are primarily equipment oriented and the only areas with any great potential for reduction in patient exposure are collimation and filtration. The rest of the regulations are mainly for operator protection. Given an adequate number of competent inspectors and a vigorous enforcement program, it is relatively easy to achieve compliance with the regulations. At this time almost everything that the regulations can accomplish in the area of patient exposure reduction will have been done.

This is not to say that patient exposure will have been reduced to the irreducible minimum. In looking at the frequency distributions of the chest ESE, it is easy to see that there is a wide variation in technique which is producing more patient exposure than there should be. I believe that it is safe to assume that the majority of practitioners are producing radiographs that are adequate for diagnosing the medical problems of their patients. On this basis, table 9 indicates that adequate radiographs can be produced with radiation exposures between 13 and 28 mR. On the same basis, 25 percent of the radiographs are produced with too much radiation. This extra radiation exposure is related to the way in which the x-ray machine is used and not to the machine parameters which are subject to the regulations.

Table 9. Weighted quartile distribution of exposure at skin entrance*, in milliroentgens - Chest (P/A) 1973-1976

Value	1973	1974	1975	1976
First Quartile	13	15	13	12
Median	20	24	18	17
Third Quartile	24	36	27	26

* Adjusted for instrument response

Once machine-oriented factors have been brought under control through enforcement of regulations, a comparison of repeat NEXT surveys can be used to judge the adequacy of people-oriented educational efforts in achieving the next portion of the goal of reducing patient exposure.

This comparison of the results of first and repeat NEXT surveys has caused us to take a hard look at our x-ray program and its emphasis. We have decided that, like those folks in Kansas City which Rogers and Hammerstein described in "Oklahoma," "We've gone about as fur as we kin go" toward reducing patient exposure by enforcing regulations of the type we now have, and our emphasis will shift to one of education of technologists and practitioners and other programs for bringing the people-oriented factors under control.

In doing so, we will continue to keep in mind the statement made by the late Dale Trout at the San Antonio meeting to the effect that the sole purpose for taking an x ray is to find out what is wrong with the patient and within rather broad limits the amount of radiation he receives is irrelevant. It is those exposures that lie outside these "rather broad limits" with which we are concerned.

In summary, there are several conclusions which can be drawn from a comparison of repeat NEXT surveys.

The first is that it will produce hard data on which to base decisions to be used in the management of an x-ray program, particularly in judging the adequacy of the program from the standpoint of reduction of patient exposure and in determining if there is a need for a shift in program emphasis. Another is that the data is good only if it has been collected carefully with particular attention to reproducibility of the collection technique and the proper application of instrument correction or calibration factors. A third is that, in order to have adequate statistical confidence in the results, the data base should be as large as possible.

POTENTIAL IMPACTS OF CONTROL PROGRAM EFFORTS ON GENETICALLY SIGNIFICANT DOSE (GSD) AND BONE MARROW DOSES

David W. Johnson
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

For many years radiological health program personnel have been surveying medical and dental x-ray equipment and writing notices of the equipment failing to comply with either the State or Federal regulations.

With the advent of nationwide surveys of population exposure to x rays and the recent developments of organ dose models, we are now able to decide in advance the potential effect of various programs on these doses before they are instituted. The data I will present today are derived primarily from the 1970 X-Ray Exposure Study, which was conducted by the Bureau of Radiological Health and the National Center for Health Statistics. I am sure many of you people here were involved in collecting data for that study.

The basic numbers to remember are the genetically significant dose of 19.6 millirads in 1970, and the mean active bone marrow dose to the adult population of 103 millirads. Keep in mind that the GSD figure is only from medical radiography (that is, it excludes fluoroscopy) and that the bone marrow dose is only to the adult population. These exclusions unfortunately were necessary because of the lack of appropriate dose models.

The action programs that I will examine today are the potential impact of requiring proper collimation, the use of male gonad shielding, and various other possible action programs, which might reduce patient exposure.

Before looking at the potential impact of these program activities, let us look briefly at the major contributors to these population doses (Fig. 1). About two-thirds of the GSD is from examinations of females, about a fourth from males, and we estimated something around 5 percent from fetal exposure.

In figure 2, we see the examinations that contribute heavily to the GSD. Note that the lumbar and lumbo-sacral spine, barium enema, pelvis, abdomen KUB, IVP, and the category "other abdominal exams" (which contains various special procedures involving the abdomen) account for almost all of the GSD.

Although it is not included in figure 2, the GSD from dental radiography was estimated to be less than 0.1 millirad, and therefore may be considered negligible as far as gonad doses are concerned.

Table 1 lists the major contributions to the population mean active bone marrow dose. Note that 77 percent was from radiographic examinations and perhaps, surprisingly, 20 percent from fluoroscopy and 3 percent from dental. Most of the bone marrow dose (about 80 percent) is from examinations of the abdomen (Table 2).

Table 2 shows the major examinations contributing to the bone marrow dose. Note that many of these are the same heavy contributors as to the genetically significant dose. We ought to keep this in mind. If we are looking for programs that would affect dose reduction, certainly abdominal exams must be considered seriously. It is interesting to note that chest and dental exams, although accounting for approximately two-thirds of all x-ray examinations in the country, contribute only about 6 percent to the bone marrow dose and essentially nothing to the GSD. There was an additional 3 percent contribution from photofluorographic

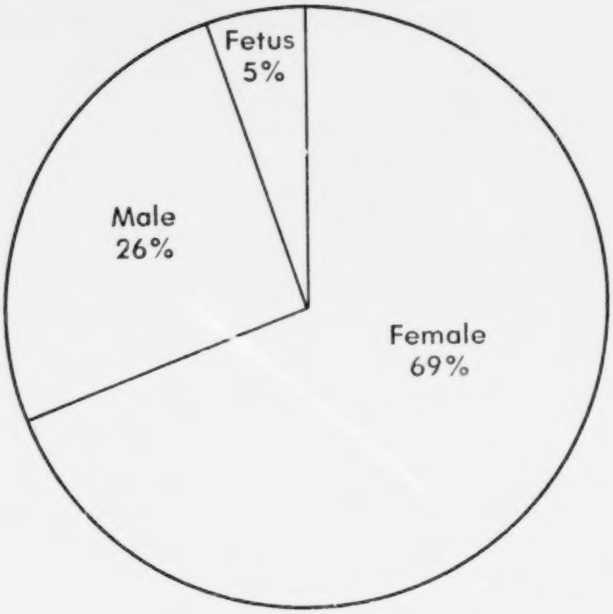


Figure 1. Contributions to the genetically significant dose from radiographic examinations by sex, United States 1970.

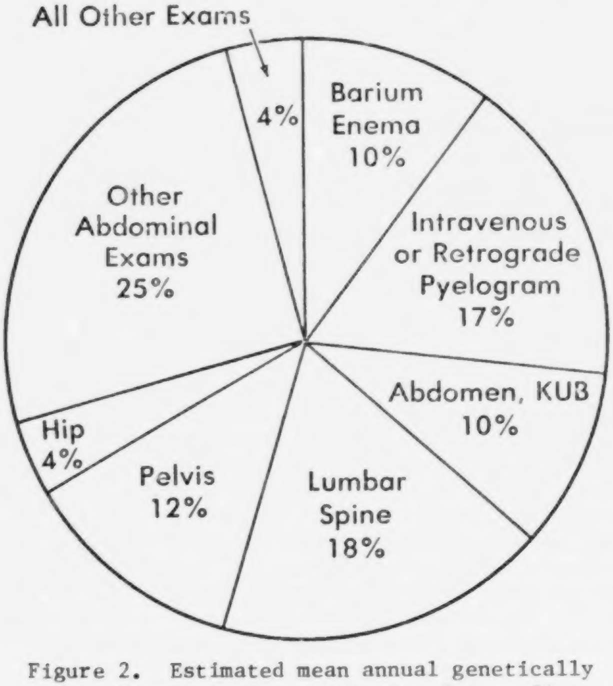


Figure 2. Estimated mean annual genetically significant dose contribution from radiographic examinations by type of examination, United States 1970.

chest exams in 1970; however, all available information indicates that there has been a substantial reduction in PFG's since then that contribution must be much lower now.

Table 1. Contributions to the annual per capita mean active bone marrow dose to dose to the adult population, U.S., 1970

Type of examination	Annual per capita dose (millirads)
Radiographic	80
Fluoroscopic	20
Dental	3
Total	103

If one were free to choose strictly on the basis of possible dose reduction, at least to bone marrow dose and the GSD, it would seem that one should not spend a great deal of time in action programs related to chest and dental, but rather should concentrate on examinations involving the abdomen.

Let us look at the potential reduction in population doses as a result of programs aimed at proper collimation. If, in 1970, all x-ray beams in radiography had been reduced to no larger than the film size, the GSD would have decreased from 19.6 to 15.6 millirads. That is a reduction of about 20 percent. This reduction is primarily because of the exclusion of the testes from the primary beam for examinations where the testes were close, but not necessarily in the direct beam, or at least not visualized on the film. Also, in 1970, there were some nonabdominal exams with huge beams that produced sizeable testicular and ovarian doses, which if collimation had been proper, would have produced essentially no gonad dose.

The effect of collimation on bone marrow dose is somewhat less dramatic than on the GSD, primarily because there is no in- or out-of-the-beam situation. Therefore, in most examinations there is some bone marrow dose involved. We estimated that reducing the beam size to no greater than the film size would have caused a decrease in mean active bone marrow dose from 103 to about 95 millirads--about 8 percent. However, the proper comparisons, since we limited this simulation to medical radiographic, would be to compare the reduction of about 8 millirads to the 80 millirads contributed by radiography.

Much has been said about the possible benefits that might be derived from a program requiring the use of gonad shielding during all abdominal area examinations in young males where diagnostic information would not be compromised.

In making this calculation, I made the following assumptions. First of all, that for all abdominal examinations of young males where the testes were either in the direct beam or within 5 centimeters of the edge of the direct beam, gonad shielding would be used. Since there is some variability in the effectiveness of gonad shielding, I assumed that there was an 85 percent reduction if the testes were in the direct beam, that there was a 50 percent reduction if the testes were within 5 centimeters of the edge of the beam, and that there was no reduction, or that the gonad shielding was not used, if they were out of the direct beam by more than 5 centimeters. Using these assumptions, we estimated that the male component of GSD would drop from about 5.1 to 2.2 millirads. This reduction is about 60 percent of the male component of GSD. However, males are not the major contributors to the GSD, so that the actual reduction to the total GSD would be more like 15 percent.

Table 2. Mean active bone marrow dose to the adult population (1970)

Examination	Mean active bone marrow dose per examination (mrad)	Annual per capita examination rate	Annual per capita dose (mrad ± S.E.)	
HEAD AND NECK				
Skull	78	0.020		1.6 ± 0.1
Cervical Spine	52	0.022		1.2 ± 0.2
Other	--	---		0.6 ± 0.2
THORAX				
Chest-photofluoro.	44	0.073		3.2 ± 0.3
Chest-radiographic	10	0.306		3.2 ± 0.1
Thoracic Spine	247	0.010		2.5 ± 0.4
Ribs	143	0.009		1.3 ± 0.2
Other	--	---		1.9 ± 0.4
UPPER ABDOMEN				
Upper GI Series (total)	5			24.3 ± 4.7
Radiographic (subtotal)	294	0.046	13.5 ± 4.3	
Fluoroscopic (subtotal)	241	0.045	10.8 ± 1.9	
Scan	167			
Spot Films	74			
Lumbar Spine	347	0.023		8.1 ± 0.8
Gall Bladder (total)	168			3.7 ± 0.4
Radiographic (subtotal)	129	0.027	3.5 ± 0.3	
Fluoroscopic (subtotal)	39	0.006	0.2 ± 0.3	
Scan	29			
Spot Film	10			
Small Bowel Series	422	0.002		1.0 ± 0.3
Other				2.1 ± 1.0
LOWER ABDOMEN				
Barium Enema (total)	875			21.2 ± 1.8
Radiographic (subtotal)	497	0.024	11.9 ± 1.0	
Fluoroscopic (subtotal)	378	0.024	9.3 ± 1.5	
Scan	268			
Spot Films	110			
IVP	420	0.024		10.1 ± 0.6
Lumbosacral Spine	450	0.013		5.7 ± 0.7
Abdomen KUB	147	0.020		2.9 ± 0.4
Other	--	---		1.2 ± 0.7
PELVIS				
Pelvimetry	595	0.002		1.4 ± 0.5
Pelvis	93	0.012		1.1 ± 0.2
Hip	72	0.009		0.7 ± 0.1
Other	--	---		1.2 ± 0.7
EXTREMITIES				
Femur	21	0.002		0.04 ± 0.02
DENTAL	9.4	0.312		2.9 ± 0.2
TOTAL				103 ± 5

In figure 3, we see the expected future number of children. Note how rapidly the expected future children drops off; after 40 or 50 years of age, it is essentially zero. This is in some ways fortunate, because this is the point when the examination rates start going up rather rapidly.

Let us now look at, perhaps, the most promising area for dose reduction; that of initiating some type of action program that might affect the exposure which patients receive. I am sure all of you are familiar with the shape of distributions of exposures for a given type of examination. Figure 4 shows a factor of 50 or more difference between the highest and lowest exposures for chest examinations. Figure 5 shows similar data for the abdomen, KUB projections showing just about as great a spread. This is very important area since, if 50 percent of the patients can be exposed with, say, around 500 mR or less, there should not be substantial numbers above 1 R.

It is very hard to say exactly what is possible in exposure reduction. In the DENT program in dental radiography, we noted that the acceptable ranges were lower than the median exposure at the time DENT was started. However, to come up with some sort of number, I assumed that all facilities use exposures very close to the median for each type of examination. If we were able to do this, I estimated that it would cause the mean active bone marrow dose to drop from 103 to 85, and that it would cause the GSD to drop from around 20 to 15. If we could combine this with a program that requires proper collimation, there would be a further reduction to about 12 for the GSD and to nearly 75 for the bone marrow dose.

In summary, we see that it is possible to lower the population genetic and bone marrow doses by 25 percent or more without even affecting the rate at which examinations are taken. Later, after we get all the operator and equipment problems taken care of, we can look into our data file and try to determine what effect we might have if the frequency of certain exams was reduced. For example, much has been said about the lateral chest view and several people have criticized it as perhaps being unnecessary. The lateral chest contributes essentially nothing to GSD and only on the order of 1 to 1.5 percent of the population bone marrow dose. Therefore, for this particular view, that is the maximum reduction we could have, even if they were eliminated, and this certainly will never happen since some of these films are probably quite beneficial.

Much of the data I presented today has been published in the GSD and bone marrow dose books by the Bureau (1,2). However, some of it has not yet been published. If you are interested in instituting some action programs and would like to discuss what possible benefits you might get from them, please give us a call. I am sure that we have some data which would be of help to you.

REFERENCES

1. Gonad Doses and Genetically Significant Dose from Diagnostic Radiology, U.S., 1964 and 1970. U.S. Department of Health, Education, and Welfare, PHS, FDA, Bureau of Radiological Health HEW Publication (FDA 76-8034).

2. The Mean Active Bone Marrow Dose to the Adult Population of the United States from Diagnostic Radiology. HEW Publication (FDA 77-8013).

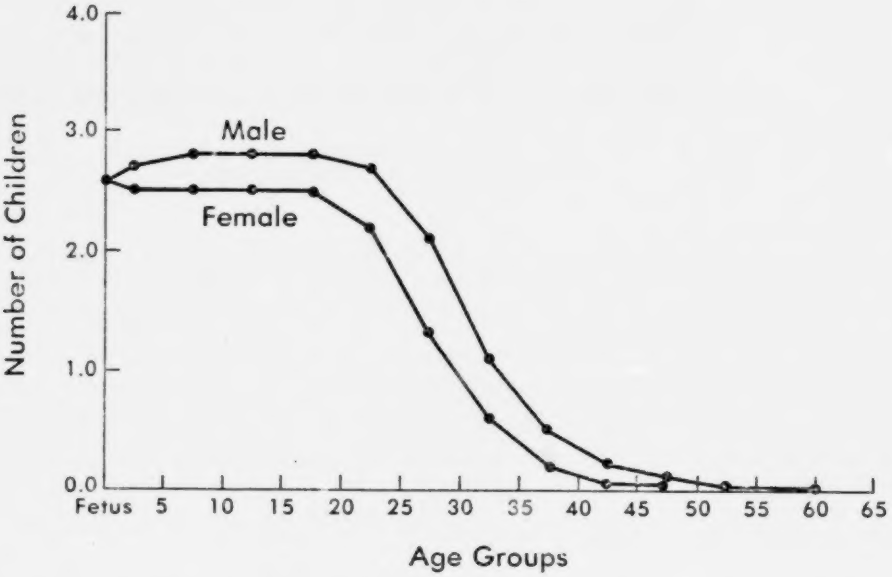


Figure 3. Expected future number of children by age and sex, United States.

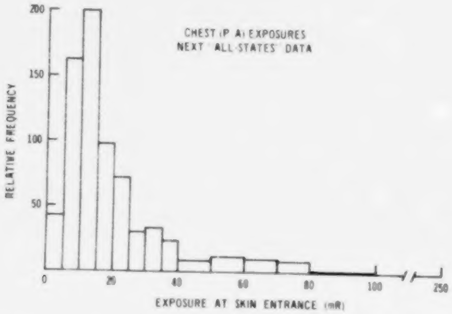


Figure 4. Frequency distribution of chest exposures.

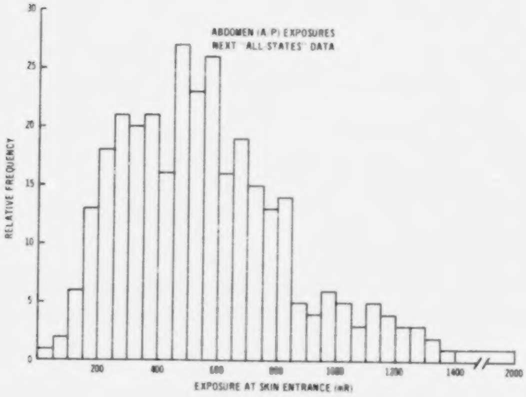


Figure 5. Frequency distriubtion of abdomen exposures.

BREAST EXPOSURE: NATIONWIDE TRENDS - PROGRESS TO DATE

Ronald G. Jans and Thomas R. Ohlhaber
Bureau of Radiological Health, FDA

As was reported last year at the Eighth Annual Conference on Radiation Control in Springfield, Illinois (1), the Breast Exposure: Nationwide Trends (BENT) program began as a result of reported instances of high patient exposure from mammography such as that reported by Henry J. Bicehouse (2) in eastern Pennsylvania. Personnel from the Pennsylvania Bureau of Radiological Health and from the District of Columbia Bureau of Occupational and Institutional Hygiene cooperated with the Bureau of Radiological Health, Food and Drug Administration (BRH/FDA), in the early design of the BENT program; also, Pennsylvania and the District of Columbia were the first two jurisdictions to participate in pilot tests of BENT, beginning late in 1975. The pilot tests were extended to three additional jurisdictions in 1976--Massachusetts, Minnesota, and New Hampshire--in order to gather additional data and to improve the survey procedures. The results reported in this paper have been summarized from data gathered in the five pilot tests.

The BENT program has been designed to provide radiation control agencies with an efficient approach to mammography quality assurance. Dosimetry cards containing thermoluminescent dosimeters (TLD's), figure 1, are mailed to mammography facilities in order to quickly provide the Agency with data on all mammography facilities within their jurisdiction while requiring minimum manpower and expense. Analysis of the data allows the agency to identify facilities where the exposure appears unnecessarily high or unusually low for the image receptor used or where the other reported data would suggest poor image quality. The radiation control agency can then select and prioritize followup surveys in view of available manpower and can advise radiologists of the mammography exposure at their facility in relation to the exposure at other facilities using similar image receptors. Subsequent identification and correction of problems will result in a reduction in unproductive radiation exposure and improved image quality. Finally, the radiation control agency can remail dosimetry cards to all mammography facilities in order to assess any reduction in exposure as well as other changes in the practice of mammography.

BENT PILOT TESTS

The five jurisdictions pilot testing the BENT program mailed dosimetry cards to over 400 mammography facilities. They have estimated that these facilities account for more than 95 percent of those conducting mammographic examinations within the five jurisdictions. The facilities were instructed to expose the dosimetry cards at the technique factors that would normally be used for a craniocaudal view of a "medium-density, medium-size" breast. The distribution of exposure measurements from the dosimetry cards are presented is figure 2.

The estimated exposure at the skin entrance site, as measured by dosimetry cards, ranged from 0.025 R to 16.6 R. (A surveyor has visited each of these two facilities and each exposure was actually being delivered with the techniques then being used in the facilities.) The mean exposure for all image receptors was 1.5 R. The median exposure was 0.9 R and 80 percent of the exposures were less than 2 R.

The 16.6 R exposure was 11 times greater than the mean exposure; and, both the 0.025 R and the 16.6 R exposures were found to be related to poor image quality at the time of the followup survey.

In order to reduce variations in exposure that would be due solely to the type of image receptor selected, the image receptors have been categorized as direct-exposure film,

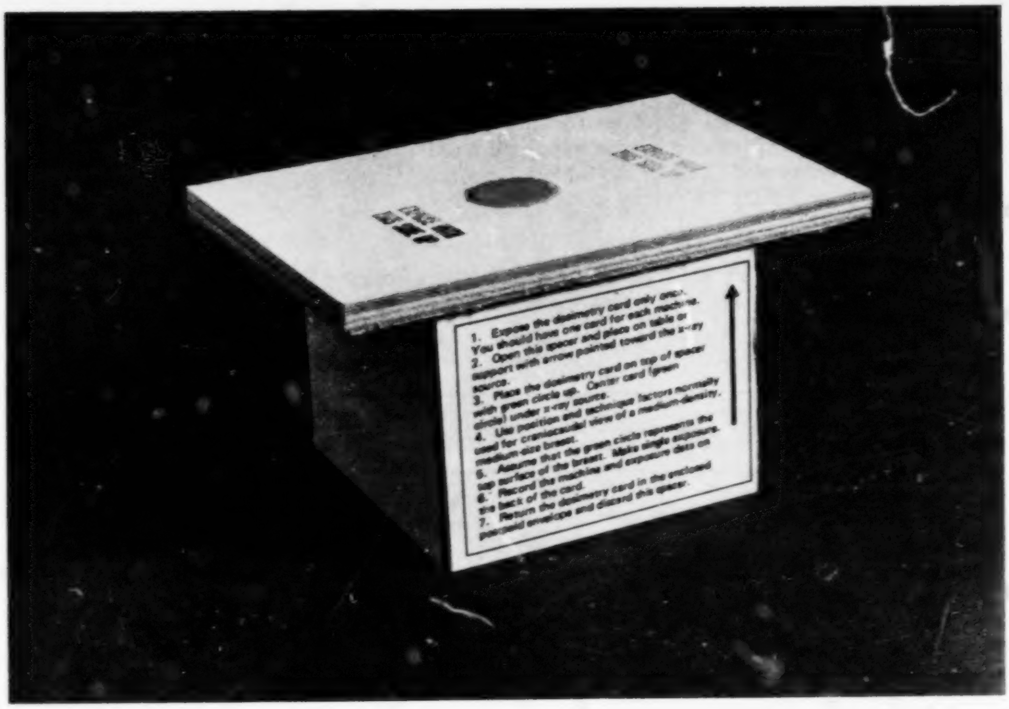

1. Expose the dosimetry card only once.
You should have one card for each machine.
2. Open this spacer and place on table or
support with arrow pointed toward the x-ray
source.
3. Place the dosimetry card on top of spacer
with green circle up. Center card (green
circle) under x-ray source.
4. Use position and technique factors normally
used for craniocaudal view of a medium-density,
medium-size breast.
5. Assume that the green circle represents the
top surface of the breast. Make single exposure.
6. Record the machine and exposure data on
the back of the card.
7. Return the dosimetry card in the enclosed
postpaid envelope and discard this spacer.

Figure 1. Dosimetry card and support used to estimate the exposure from mammography x-ray units.

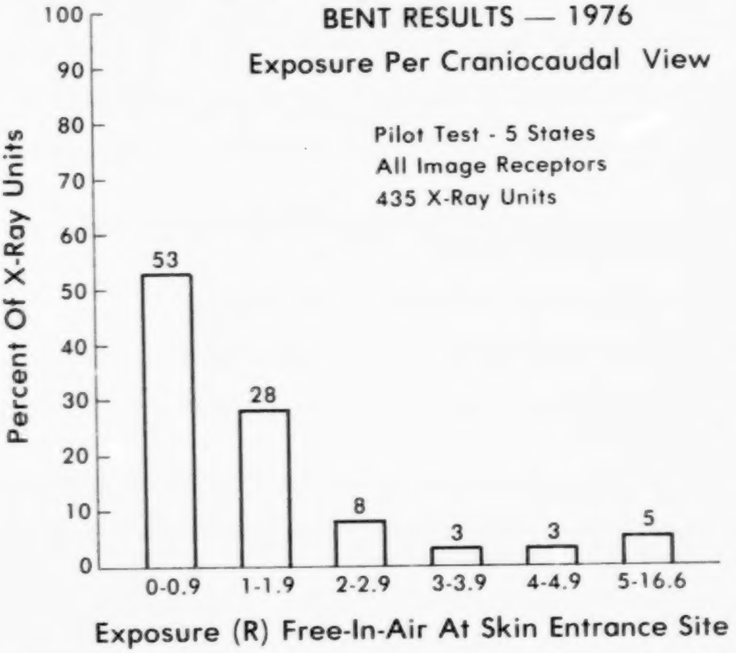


Figure 2. Distribution of exposure free-in-air at skin entrance site from a single craniocaudal view of a "medium-density, medium-size" breast in 5 States pilot testing the BENT program.

film/screen combinations, and Xeroradiography. The mean craniocaudal exposure for each of these categories is presented in table 1.

The mean craniocaudal exposure for the 162 x-ray units that were used with the Xerox system was heavily influenced by the exposure from 25 x-ray units that apparently contained molybdenum anodes and little or no added aluminum filtration. The mean craniocaudal exposure for the remaining 137 x-ray units was 1.33 R.

Table 1. Exposure (R) free-in-air at the skin entrance site from a single craniocaudal view by category of image receptor in five States (preliminary data as of 3/11/77).

Image receptor	Number of x-ray units	Mean exposure (R)
All Types	435	1.49
Direct Exposure Film	75	3.21
Film/Screen Combinations	198	0.60
Xeroradiography	162	1.80

In order to suggest facilities for followup surveys, criteria were developed that could be applied to the entrance exposure, reported kVp, type of image receptor, and type of film processing obtained from the dosimetry card. The criteria that were developed are not intended to be used as exposure guides or as limits, but as action guides that would lead to the collection of additional data and information that could be used in an evaluation of the mammographic system. Manufacturer's recommendations, published information, opinions from radiologists using the image receptors, and the experiences of State surveyors during followup surveys were considered in establishing the criteria, and the criteria may change as other data become available.

If a State elected to conduct a survey at one of the facilities suggested for followup, it was intended that the surveyor would:

- verify the reported data and exposure measurement,
- attempt to identify the causes of unproductive exposure, if any, and
- offer recommendations to assist the facility in correcting the problem or in seeking further assistance.

The criteria used to suggest facilities for followup surveys were as follows:

1. Exposure. Exposures were categorized as apparently high or unusually low if they met any of the following conditions:

Image receptor	Anode material	Unusually low exposure	Apparently high exposure
direct exposure film	all	X < 1.00R	X >3.00R
conventional film/screen combinations	unknown	X <0.15R	X >1.80R
	W	X <0.15R	X >0.90R
	Mo,W/Mo	X <0.30R	X >1.80R
rare earth* film/screen combinations	unknown	X <0.10R	X >1.20R
	W	X <0.10R	X >0.60R
	Mo,W/Mo	X <0.20R	X >1.20R
Xeroradiography	unknown	X <0.50R	X >3.00R
	W,W/Mo	X <0.50R	X >2.50R
	Mo	X <1.00R	X >3.00R

* or equivalent speed conventional systems

2. kVp. kVp's were categorized as apparently high or unusually low if they met any of the following conditions:

Image receptor	Unusually low kVp	Apparently high kVp
all film	kVp <26	kVp >34
Xeroradiography	kVp <35	kVp >50

It should be noted that the criteria are applied to the reported or "nominal" kVp. The actual relationship between the "nominal" kVp and the actual kVp that could be measured for the unit is unknown; therefore, caution must be used when changing technique factors.

3. Image Receptor. Image receptors were classified as atypical if the facility indicated the use of film or film/screen combinations, other than direct expsoure film or film/screen combinations marketed specifically for mammography, e.g., Cronex 4 or RP/M films with par-speed screens would be classified as atypical.

4. Film Processing. Film processing was categorized as atypical if the facility reported automatic processing of film recommended for manual processing or indicated manual processing of film recommended for automatic processing.

After the above criteria were applied to the data collected in the five pilot tests, 190 x-ray units in 180 different facilities were suggested for followup surveys. Sixty-four of these units, used to examine 25 percent of the patients reported by the facilities, gave an exposure that appeared unnecessarily high for the type of image receptor used. The mean exposure for these units was 5.06 R, more than 3 times the mean exposure for all x-ray units. Seventy x-ray units gave an exposure which appeared unusually low, mean exposure 0.22 R, and 56 x-ray units had an indication(s) for followup other than high or low exposure, mean exposure 1.09 R. The 126 x-ray units with low exposure or other indications for followup were used to examine 17 percent of the patients reported by the mammography facilities.

Followup surveys have been conducted at facilities selected by the jurisdictions. In most cases, facilities with apparently high exposure have had identifiable problems which were correctable. Of the x-ray units with apparently high exposure, 25 were used with the Xerox system, 16 with film/screen combinations, and 23 with direct exposure film. The most common cause of high exposure with the Xerox system was the use of molybdenum anodes with little or no added aluminum filtration. High exposure with direct exposure film or with film/screen combinations was most often related to the use of very low kVp and high mAs, the so-called "high-density" technique that requires the use of special "bright" or "hot" lights to penetrate the added density on the film. The added density is gained at the expense of 2 to 4 times the exposure required for normal density films read on a standard view box. After considering the characteristics of most of the film/screen combinations currently available for mammography, it appears that "high density" techniques may actually result in a loss of information (3,4). In most cases, it has been possible to reduce exposure and maintain image quality on film/screen systems by adjusting the technique factors. Exposure reduction while maintaining image quality has been less successful on direct exposure film systems because added detail is recorded at the higher densities.

After surveys of many of the x-ray units identified for followup on the basis of low-exposure or other indicators for followup, it is estimated that two-thirds of these units have correctable problems that are resulting in poor image quality. It is estimated that the other one-third of the units were identified for followup on the basis of incorrectly reported data or incorrectly exposed dosimetry cards. The more common causes of poor image quality were high kVp used with film (often, 40 to 45 kVp or more), large amounts of added aluminum filtration with film (1 mm aluminum, first HVL or more), and, less commonly, atypical film/screen combinations for mammography, such as double emulsion film and par-speed screens.

Based upon the followup surveys that have been conducted in the five jurisdictions pilot testing BENT, approximately 15 percent of the x-ray units gave exposures that were unnecessarily high for the type of image receptor used and approximately 20 percent of the x-ray units had problems that were resulting in poor image quality. Corrections and changes made by individual facilities have reduced exposure by as much as 25 to 75 percent (95 percent in one facility) and/or improved image quality. It is projected that the mean craniocaudal exposure for all x-ray units may have decreased by as much as 20 percent. The five pilot jurisdictions will be remailing dosimetry cards in order to evaluate any changes that may have occurred in the practice of mammography at these facilities.

DOSIMETRY

Exposure measurements in the BENT program are made with TLD (LiF,TLD-100) and the MDH Industries 1015 x-ray survey instrument. The TLD and the MDH have been evaluated for energy dependence. The evaluation consisted of exposure to x rays with both monoenergetic and multienergetic spectra which bracketed the mammography range--approximately 0.3 to 3 or more mm Al, first half-value layer (HVL) (5). Figures 3 and 4 display the correction factors as determined from the exposures. Based upon a consideration of these correction factors over the energy range normally used in mammography, the maximum error due to the energy dependence of the TLD is estimated to be ± 15 percent. Similarly, the maximum error because of the energy dependence of the MDH is estimated to be ± 5 percent.

Each dosimetry card used in the pilot test of the BENT program contained 2 TLD's. A 1-mm thick, aluminum disc, 1.9 cm in diameter, was positioned beneath the TLD to minimize variations in backscatter. The TLD's were calibrated with the aluminum backing in place against free-in-air exposure measurements made with a Victoreen 415 Intercomparison Standard calibrated by the National Bureau of Standards. Therefore, application of the correction factors to the TLD's in the dosimetry cards, which also contain the aluminum backing, yielded an exposure estimate that is essentially free-in-air.

The dosimetry cards that are used in States beyond the five pilot tests will contain 2 sets of 2 TLD's each, separated by 3 mm of aluminum. Calibrations are performed in the same manner as for the pilot test. Determination of the ratio of the entrance exposure and

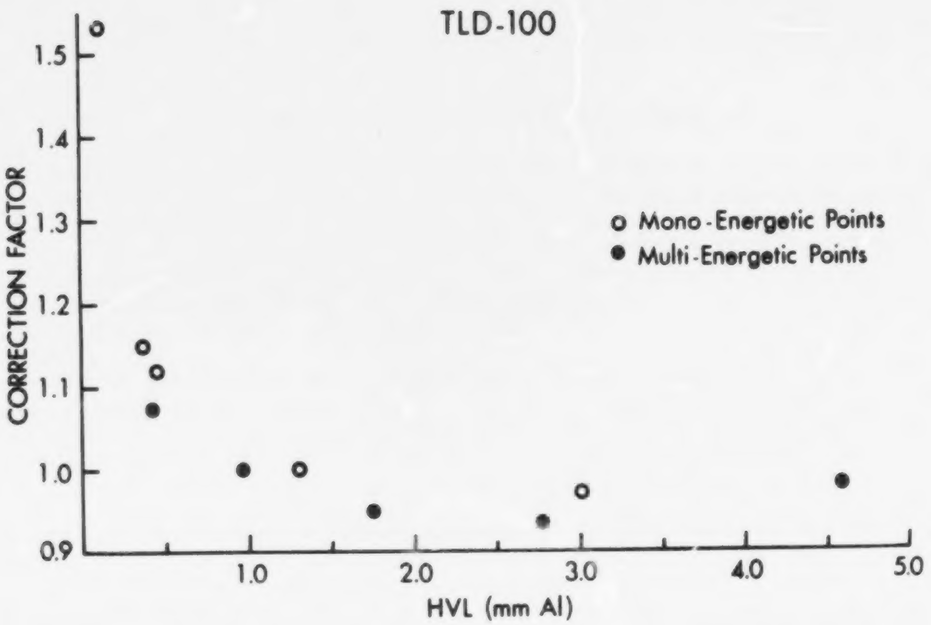


Figure 3. Energy dependence of TLD 100. The multienergetic spectrum is normalized to one at 0.96 mm Al HVL. Likewise the monoenergetic spectrum shows one a 1.3 mm Al HVL.

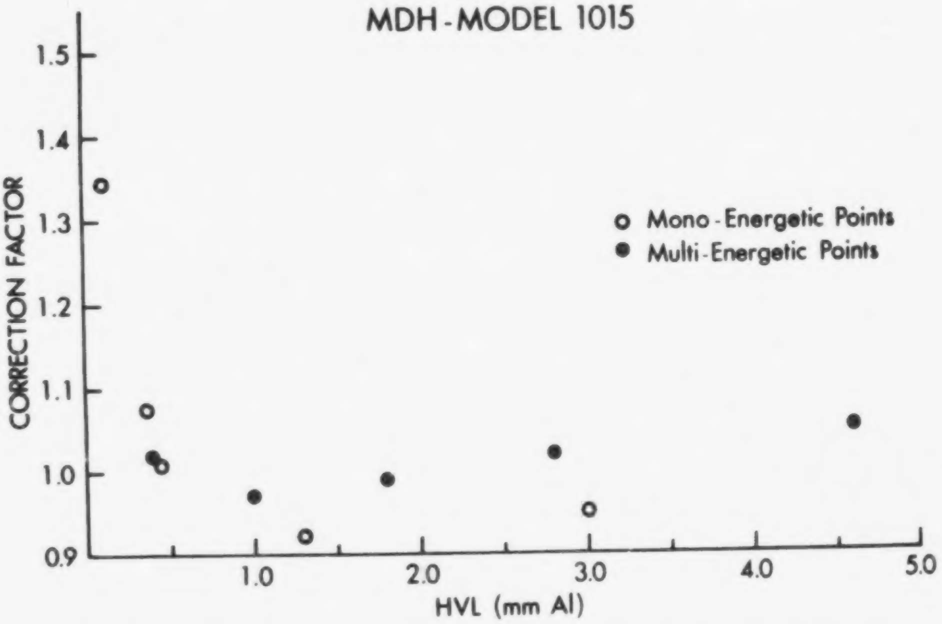


Figure 4. Energy dependence of MDH 1015. The multienergetic curve is not normalized but indicates actual reading. The monoenergetic curve is slightly displaced low due to the experimental set-up.

transmitted exposure and application of the ratio to reference curves, developed for several spectra and a range of kVp, provide an estimate of the first half-value layer.

EXPANDED BENT IMPLEMENTATION

The Bureau, through an Interagency Agreement with the National Cancer Institute, is accelerating the process of making the BENT program available to State radiation control agencies. BRH provides a participating agency with dosimetry and equipment support as well as training and technical assistance during the conduct of the program. The agreement was effective beginning November 1, 1976, and it is the goal of the Bureau to support all State radiation control agencies in the implementation of the BENT program by September 30, 1978.

As of June 1977, radiation control personnel from 13 States (18, if the pilot States are included) have received training in mammography quality assurance procedures. Ninety-six trainees have attended the 1- to 2-day training sessions which have included lectures on the physics of mammography as well as actual case histories of surveys conducted by State personnel. The training also includes practice surveys at mammography facilities.

It is estimated that 4,000 to 5,000 x-ray units are used for mammography nationwide. In the five pilot tests, data were gathered on 450 x-ray units. During April 1977, dosimetry cards were supplied to four States - Georgia, California, Oregon, and Wyoming. New York City and Idaho received dosimetry cards in June and cards are scheduled for additional States in July and August. By July 1977 it is projected that TLD exposure measurements will have been made on 25-29 percent of the mammography units in the Nation (includes measurements made on mammography units in the pilot tests). As the dosimetry cards are returned, exposure distributions will be developed similar to those presented for the pilot jurisdictions.

FUTURE ACTIONS

The Bureau is continuing to schedule training sessions and dosimetry support for radiation control agencies implementing the BENT program. It is anticipated that States will have collected data on approximately 40 percent of the mammography units in the Nation by the end of 1977 and that followup surveys will have been started at facilities where the exposure appeared unnecessarily high or unusually low. Data will be gathered on additional x-ray units during 1978.

ACKNOWLEDGEMENT

Grateful appreciation is extended to the following radiation control agency personnel who have contributed to the design of the BENT program and who have conducted the pilot tests in their jurisdictions, during which the data reported in this paper were collected: Richard A. Lane, Chief, and Dr. An-Liang Soong, District of Columbia Bureau of Occupational and Institutional Hygiene; Donald J. McDonald, Chief, Henry J. Bicehouse, James Copenhaver, Stuart Levin, Division of Radiation Control, Pennsylvania Bureau of Radiological Health; Gerald S. Parker, Assistant to the Commissioner (Radiological Health), Ralph Giordano, Massachusetts Department of Public Health; Ms. Alice Dolezal, Chief, Thomas Hensch, Section of Radiation Control, Minnesota Department of Health; and John R. Stanton, Director, Diane Tefft, New Hampshire State Radiation Control Agency.

REFERENCES

1. Jans, Ronald G. "The Options: Mammography Quality Assurance Program." Proceedings of 8th Annual Conference on Radiation Control: Radiation Benefits and Risks: Facts, Issues, and Options. FDA 77-8021.

2. Bicehouse, Henry J. "Survey of Mammographic Exposure Levels and Techniques Used in Eastern Pennsylvania." Seventh Annual National Conference on Radiation Control - Assuring Radiation Protection. FDA 76-8026.

3. Halm, D.M., A.G. Haus, and J. Bernstein. "Evaluation of the Proper Photographic Density Range for Lodose Mammography." Radiologic Technology 48:3 (Nov./Dec. 1976).

4. Selin, K. and S. Reichman. "High-Density Failure of Radiographic Films." Acta Radiologica Vol. 18 (January 1977).

5. Ohlhaber, T.R. and P.M. Skeeter. "BENT Surveys - Dosimetry." Medical Imaging 2:2 (2d Quarter, 1977).

FEDERAL GUIDANCE FOR DIAGNOSTIC X RAYS

James E. Martin, Ph.D.
Deputy Director, Criteria and Standards Division
Office of Radiation Programs, EPA

Many of you will recall that last year about this time I reported to you that we had just published in the FEDERAL REGISTER an announcement of availability of the report of the Subcommittee on Prescription of Exposure to X Rays, and that we were working actively on the report of a Subcommittee on Technique. That report was published in July 1976 and announced in the FEDERAL REGISTER for comment.

The Interagency Working Group, which was formed by the administrator to address this question at the Federal agency level, reviewed the results of the two subcommittee reports, and the public comments on them. From this, the Interagency Working Group developed a consolidated report that arrived at recommendations for Federal Radiation Guidance for Diagnostic X Rays and proposed those to the Administrator of EPA to recommend to the President. There were 15 recommendations in the prescription subcommittee's report, 14 in the technique committee's report, and these were consolidated to combine some of the repetitive points into 12 basic recommendations. These have been under consideration since last fall. The report was published in October 1976, but was not announced until the recommendations were published in proposed form January 21, 1977, in the FEDERAL REGISTER.

The intervening period was devoted to clearance or review from the various Federal agencies involved, and with resolution of their comments. The Interagency Working Group considered throughout its efforts that it was desirable and possible to reduce radiation exposure from the use of diagnostic x rays in Federal facilities and developed the recommendations to achieve those ends.

Without going through all of the 12, I would just quickly summarize that the recommendations on prescription of x-ray examinations state that the ordering of such examinations should be performed only by qualified personnel, should be based on clinical evaluation of individual patients, and should attempt by appropriate procedures to avoid unnecessary examinations.

Screening programs were addressed from the standpoint that those that involved routine exposures of large populations should not be performed unless a prior determination had been made by the sponsoring agency that the medical benefit outweighed the radiation risk and the cost. Equipment and technique should conform to generally accepted standards and guidelines for good practice, and performance should be maintained through the use of quality assurance programs, including the establishment of numerical guides or standard examinations to be used for judging the need for action to reduce exposures. I think we have seen a very good example of that sort of intent with the BENT program; BRH and the States are to be commended for their efforts on this.

The recommendations were developed in a manner essentially the same as they had been done in the past by the FRC, that is by an interagency Working Group comprised of the effected Federal agencies. For the first time, however, the public has been invited to participate by providing comments on the background reports and on the recommendations before they were sent forward for Presidential approval. The response to the invitation for comments has been generally favorable and we have, I believe, resolved in a satisfactory manner all the matters raised of a technical nature. The Surgeons General of the three Armed Forces, the Veterans Administration, the American Academy of Pediatrics, the Health Physics Society, and the American Society of Radiologic Technologists endorsed the recommendations.

We have received adverse comments largely resulting, I believe, from a disagreement by some over the division of responsibility between EPA and HEW regarding this provision of radiation protection guidance. We have received adverse comments from the Department of Health, Education, and Welfare principally over the jurisdiction of whether EPA should be doing this. The central argument has been that EPA should not extend its Federal guidance authority to include medical radiation, and this view was supported in the public comments by the American College of Radiology, the American Dental Association, the American Hospital Association, and the American College of Nuclear Physicians.

In our judgment, as you might well imagine, this is contrary to what we believe was the basic intent of the Federal guidance function. We believe that the same argument could equally be advanced by Federal agencies involved in energy or other areas, and would rapidly lead to the demise of this comprehensive national radiation protection function

We believe that the jurisdictional issue has been properly addressed because EPA and HEW formulated in the latter part of last year a memorandum of understanding that recognizes the various roles of the two agencies, and sets forth a mechanism for the development of radiation protection guidance in the healing arts. We believe that this guidance was developed basically within the spirit of that memorandum, had it been in effect at the time that we started the program, and certainly has been carried out in the spirit of the memorandum since that time.

In closing, I would like to emphasize to you the point that I made last year when I reported on this subject, and that is that EPA fully recognizes the efforts and the programs of the States and the Bureau of Radiological Health in this area and wants only to be a cooperative adjunct to these efforts by carrying out basic radiation protection guidance for Federal agencies. We sincerely hope that this effort will help to achieve the basic goal that all of us seek, and that is the avoidance of all unproductive exposure to the population from the diagnostic uses of x rays.

THE STATES' VIEW OF FEDERAL GUIDANCE REPORT NO. 9

David K. Lacker
Radiation Control Branch
Texas Department of Health Resources

In this discussion of Federal Guidance Report No. 9, I will not be attempting to represent the views of all 50 States and the territories. I have not polled the States for comments, and the number of discussions with other States has been limited. The title of the presentation therefore should probably have been "One State's View" with a few others' ideas incorporated.

On that basis then, I hope that you will not take violent action against me if I do not express your particular opinion. If you feel strongly that your view should be expressed, I am sure that Dr. Martin would be willing to receive your letter. I was about to say he would be happy to receive your letter but since I have not discussed this with him, that may not be the case. If your letter is returned unopened you will know that he was not even willing to receive it.

For the purpose of this presentation, I will discuss each section of the guide in sequence with major areas needing further development or clarification receiving criticism which I hope is constructive since that is my intent.

The discussion on the prescription of x rays introduces the concept of "clinically unproductive procedures" and encourages their elimination. The report then lists five major factors involved in ordering unnecessary x-ray examinations and proceeds to discusss various mechanisms through which unproductive exams might be performed. I believe there should be more specific information in the text to define the term "unproductive procedures."

The section "Qualifications to Prescribe X Rays" appears to be rather permissive to those of us not familiar with staffing requirements for Federal facilities, the phrase "... only by Doctors of Medicine or Osteopathy who are eligible for licensure in the United States..." is confusing since in most, if not all, State regulations, the application of radiation to humans must be "by or under the supervision of an individual licensed to engage in the healing arts." It seems that similar guidance for Federal facilities would be more appropriate. Even more permissive is the statement that permits "properly trained and physician supervised" physician assistants, nurse practitioners, and persons in postgraduate medical training status to prescribe x-ray examinations. There are no criteria to indicate the training that should be considered as minimum to be proper.

The discussion of "Screening and Administration" programs is generally well done. The "Mammography" discussion covers almost two pages to inform that mammography screening policies should be reviewed in light of continuing development of new information on mammography. Since mammography is such a dynamic issue, perhaps the lengthy information is appropriate at this time.

The section entitled "Self-Referral Examinations" does not clearly indicate what is meant by the title term. It speaks of x-ray examinations performed by nonradiologic clinicians and examinations by equipment operators, and civilian contract services all in the same paragraph. Subsequent paragraphs do not clarify the term but further confuse one by leaving the impression that if a physician who is not a radiologist prescribes an examination on his patient, it is a self-referral. Self-referral needs to be better defined if it is to be understood.

I have no specific comments on the sections on "Equipment," "Technic," and "Dental Radiography"; they seem appropriate for the intended purpose.

The summary and recommendations section lists 12 recommendations for guidance to Federal agencies and are concise statements of various factors discussed earlier in the guidance report. If users read the entire report they can be useful in minimizing unnecessary exposure. Recommendation 1 should contain more specific information regarding the limited procedures for which exceptions may be made allowing physician assistants, nurse practitioners and physicians in post-graduate training to prescribe them. The paragraph should also contain the physician supervision requirement described in the earlier text.

In summary, the guidance report is a commendable step in the right direction. There are some terms used that need to be better defined (e.g., clinically unproductive, self-referral clinicians, diagnostician). The report would be of more help if it provided more specific examples of methods to achieve the desired action. The choice of a different format for presenting the information might make for more effective implementation. Presentation of the information in a format such as recommendation 1. - discussion, recommendation 2. - discussion, would provide a more coherent picture of what is expected for each recommendation. After all, the ultimate goal should be to provide the necessary information that allows us to safely venture on our way, and be so guided that we cannot stray.

DISCUSSION

MR. GREEN: I would like to address a question to the first speaker regarding the NEXT program and the application of the NEXT program. My question really relates to your tests involving the PA Chest examination; I was wondering how may x-ray units in Oklahoma, or what percentage of units that you looked at used photo-timing and would this be a good examination to use the next round.

MR. CRAIG: I cannot give you exact figures as to the proportion of the machines using photo-timing. However, there are no photo-timed PA Chests in our data because there are no procedures for surveying the photo-timed unit. The Bureau is working on this. The NEXT task force is working on it very diligently.

We recognize it as a weakness in the NEXT program and the only answer is that in the future we hopefully can include it.

MR. GREEN: My concern is, at least in British Columbia, it seems that 80 percent of the chest examinations completed are done using photo-timing and so the next point is what is the relevancy of using a PA Chest as part of the NEXT program?

MR. CRAIG: Paul, can you give some indication as to what the proportion of the chest might be taken on photo-timing?

UNIDENTIFIED SPEAKER: Oh, I would say very few. It is usually just in large hospitals that might have 20 or 30 units and they might have one chest room where it is completely photo-timed; but in small clinics and M.D.'s private offices, there is usually no photo-timing equipment at all.

NRC TASK FORCE REPORT ON REVIEW OF THE FEDERAL/STATE PROGRAM FOR THE REGULATION OF COMMERCIAL LOW-LEVEL RADIOACTIVE WASTE BURIAL GROUNDS

William P. Bishop, Michael J. Bell, Kitty S. Dragonette and John A. Adam
Waste Management Program
U.S. Nuclear Regulatory Commission

(Presentation made by John A. Adam)

The NRC Waste Management Program was organized in mid-1975. A waste management staff has been assembled and been given organizational identification and structure. Within the past few months, the staff was split into two branches and the position of the Assistant Director for Waste Management was established in the Division of Fuel Cycle and Material Safety. The High-Level and Transuranic Waste Branch will have responsibilities in the areas of spent fuel (as waste), high-level waste, transuranic waste, and repository licensing. The Low-Level Waste Branch will have responsibilities in the areas of low-level waste, mill tailings, decommissioned facilities, and licensing of disposal other than repositories.

The Commission's overall Nuclear Waste Management Program is designed to address four major objectives:

1. Provide objective performance goals (technical, social, economic, and environmental) against which nuclear waste management programs and strategies can be evaluated.
2. Provide a framework of regulations, standards, and guides for management of nuclear waste. This framework will have to be supported by a comprehensive series of environmental impact statements.
3. Develop a methodology for implementing goals and regulations and the required data base.
4. Be capable of performing licensing reviews of proposed waste management systems on a timely basis.

Two recent efforts have provided major program directions for the NRC's Low-Level Waste activities. First, the environmental impacts of the waste management portion of the LWR fuel cycle, which are tabulated in Table S-3 of 10 CFR Part 51 of our regulations, were recently reevaluated. Second, an NRC task force has completed review of the programs used by the NRC and State governments to regulate low-level waste burial grounds.

In November 1972, a document entitled "Environmental Survey of the Nuclear Fuel Cycle" (WASH-1248) was published by the AEC. Its purpose was to establish a technical basis for informed consideration of environmental effects of the uranium fuel cycle and environmental impact statements for individual LWR's. In the survey, the uranium fuel cycle was treated generically. Environmental impacts were tabulated and promulgated as a final rule for referencing (Table S-3) on April 22, 1974 (39 FR 14188).

In July 1976, the United States Court of Appeals for the District of Columbia Circuit approved the overall generic approach but found that the rule was inadequately supported by the record in two aspects--impacts for reprocessing of spent fuel and impacts from radioactive waste management. In response, the Commission directed NRC staff to expeditiously prepare a well-documented supplement to the Survey to address the two deficient areas. The result was NUREG-0116, entitled, "Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle." Public comments were solicited.

The comments and NRC responses were published as NUREG-0216, entitled "Public Comments and Task Force Responses Regarding the Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle." The three documents collectively serve as the record upon which the Commission based its decision on amended Table S-3 published as an effective interim rule in March 1977 (42 FR 13803).

The generic treatment of the waste management portion of the fuel cycle was intended as a reasonable assessment of likely impacts and was limited in scope to correspond to the court findings. For example, the treatment included low-level waste but not uranium mill tailings since the findings of deficiency did not apply to mill tailings. Further, the time frame was the next 10 years and no economic costs, benefits, or assessment of alternatives were included.

Calculated Impacts for Low-Level Waste - The environmental impacts of disposal of non-transuranic low-level wastes were determined. The collective treatment of LLW in the Table S-3 documents involved a set of assumptions with respect to waste, waste treatment, and disposal at a model site.

The term low-level waste is used to refer to all solid radioactive waste other than high-level waste, transuranic waste, and mill tailings, A limit of 10 nanocuries/gram was assumed as a working number to limit transuranic content. The only other limits assumed were that PWR core barrels and shrouds from decommissioning of reactors would not go to the burial grounds because of their high specific activity. The volumes and activities of low-level waste buried normalized to a per reactor year for normal operation are shown in table 1. The contributions from various fuel cycle facilities are included. The LWR's during operation and during decontamination and decommissioning are the major contributors.

Table 1. Low-Level waste buried per RRY (normal operation)

	UF_6	U enrich	fuel fab.	LWR	Reproc.[a]	Spent fuel storage	D/D
Volume (M^3)	53	30	28	630	7	.21	360
Radioactivity (Ci)[b]	6	-	-	9,130	-	54	1,520

[a] Applies only to uranium-recycle option.

[b] Nonentries, indicated by dashes, represent amounts that are identifiable but are insignificantly small.

Operating reactor wastes were assumed to be treated in the following fashion. Dry solid materials were compacted and packaged in 55-gallon drums. Liquid or wet waste were assumed to be solidified in cement or urea formaldehyde and packaged in 55-gallon drums. No volume reduction other than compaction of solids was assumed. No impacts were attributed to the treatment phase since the treatment is covered in the individual facility analyses.

Wastes were assumed to be disposed of by commercial shallow land burial. The characteristics and operation of the model burial site were selected to illustrate and illuminate the issues involved in shallow land burial. The site characteristics and operational practices were drawn from experience with existing sites. Very simply, wastes are stacked or dumped into excavated trenches 20 to 30 feet deep, up to several hundred feet long, and 30 feet wide and covered with earth backfill. The filled trenches are capped with compacted earth.

Some of the key features of the model site itself were:

1. Rural, but accessible location;
2. An annual precipitation of about 40 inches;
3. Water table about 50 feet (compared to 30 foot trench depth);
4. Little potential for flooding, erosion, or surface water accumulation;
5. Soil of adsorbative capacity such that any leached nuclides move slower than the ground water; and
6. Sufficient soil permeability to prevent bathtub effects.

Some of the key operational assumptions were:

1. Engineered surface water control (grading primarily);
2. Active maintenance of trench caps;
3. Conduct of an environmental monitoring program;
4. Secure operations area;
5. Buffer zone around the operational area; and
6. Health physics program to control contamination.

Calculated Impacts - Based on the assumed site characteristics and operational parameters, no routine effluents are expected from a shallow land burial site. A summary of the environmental impacts from disposal of low-level waste produced per reference reactor year is presented in table 2. The land use requirements indicated were based on the burial of approximately 10,000 cubic meters of waste per acre and the commitment of the actual trench area. The simplicity of the facilities and operations at the sites result in minimal use of water and energy resources.

Table 2. Summary of environmental impacts of disposal of low-level wastes (Non-TRU) per RRY

Natural resource use	Burial
Land (acres)	
Temporarily committed	0.3
Undisturbed area	0.2
Disturbed area	0.1
Permanently committed	0.1
Overburden moved (millions of MT)	0.001
Water (millions of gallons)	0.0
Fossil fuel	
Effluents - chemical (MT)	
Gases (including entrainment)	0.0
Liquids	0.0
Solids	0.0
Effluents - radiological (curies)	
Gases (including entrainment)	0.0
Liquids	0.0
Solids (buried)	
Other than high level	11,000
TRU and HLW	0.0
Effluents - thermal (billions of Btu)	0.0

In judging likely impacts, the consequences of operational and accidental releases were included. Primarily, the accidental and natural phenomena scenarios involved limited unburied material and minimal offsite transport. Both the operational period and the longer term control period (approximately 300 years) were addressed. Active surveillance and maintenance of the site during the longer time period was also assumed.

The 11,000-curie entry in table 2 for buried solids was included because the waste was placed in the geosphere although not directly into the biosphere (i.e.; the human environment). The wastes are not totally isolated but the releases and dose commitments are small. The preliminary results of groundwater modeling and sensitivity calculations were presented in Appendix H of NUREG-0216 and are the basis of the dose value. The sensitivity of groundwater migration to parameters such as leach rates, soil type, groundwater velocities, and distribution coefficients was studied. The results showed that groundwater movement of radionuclides through saturated silt and clay soils is sufficiently slow to allow significant decay in reasonably short distances. Nothing in the preliminary calculations indicated that shallow land burial is not an acceptable disposal method, even in humid climates.

Actual Experience - The environmental impacts from existing sites have also been small even though operational difficulties have been experienced at some sites. The existing commercial burial sites are listed in table 3. The sites have varying physiographic, physical, and operational characteristics. Appendix H of NUREG0216 presents onsite and offsite monitoring data from the commercial sites over a period of several years. The results of several recent studies that analyze the environment data are also included. The design of the monitoring systems, while not real, appears sufficient to detect releases or problems. Data from South Carolina and Illinois do not indicate that releases are occurring. Data from Kentucky and New York do not indicate that significant subsurface migration is occurring or that long-term problems necessarily exist.

Table 3. Commercial Waste Burial Grounds

Location	Operator	Year licensed	Currently licensed by
Beatty, Nev.	Nuclear Engineering Co., (NECO)	1962	State & NRC*
Maxey Flats, Ky.	NECO	1962	State
West Valley, N.Y.	Nuclear Fuel Services	1963	State
Hanford, Wash.	NECO	1965	State & NRC*
Sheffield, Ill.	NECO	1967	NRC
Barnwell, S. Caro.	Chem-Nuclear Systems, Inc.	1971	State & NRC*

*NRC Licenses only special nuclear material.

At the New York and Kentucky sites, the site characteristics coupled with operating and trench engineering practices used in the early years of operation, have resulted in small releases of radioactivitiy and potential small exposures to offsite population groups. At a third site, Nevada, the diversion of contaminated particles from the site has also resulted in small exposures to some members of the surrounding population. The problems have not resulted in risk to the public health and safety and corrective actions are being taken. Several studies are currently underway at the humid sites to further define their performance and identify and assure appropriate corrective actions. These operational difficulties and corrective measures are discussed in Appendix H of NUREG-0216.

Remaining Issues - The table S-3 efforts resulted in the illumination of a number of remaining issues which need to be factored into the NRC program development. Some of the more important are:

1. Better quantification of potential releases is needed. Although all indications are that releases and potential releases from the sites are insignificant, additional studies, modeling, and analyses are necessary to state these findings with more assurance.

2. Performance standards to formalize collective best judgments are needed. A formalized regulatory framework, including the standards and criteria, is needed to assure that the future performance will be equivalent to that assumed for the model.

3. Alternatives to shallow land burial need to be studied.

4. Waste classification needs resolution. For example, the formalized rule to determine cutoff limits for transuranics is needed to verify or replace the 10 nanocuries/gram criteria assumed.

5. Non-LWR fuel cycle waste need to be included.

Nontechnical issues were addressed briefly in the table S-3 efforts, but the primary focus was on the technical considerations. Just the reverse is true for the Federal/State regulatory program review.

FEDERAL/STATE REGULATORY PROGRAM REVIEW

Background - A nuclear Regulatory Commission Task Force studied the programs used by the NRC and State governments to regulate disposal of commercial low-level radioactive waste. The study was part of the NRC reexamination of the technical and regulatory bases for low-level waste management and also covered the issues raised by the U.S. General Accounting Office (GAO), the Joint Committee on Atomic Energy (JCAE), and the House Committee On Government Operations. The Task Force findings were published as NUREG-0217, "NRC." To solicit public comments, the body of the report was also published in the FEDERAL REGISTER on March 10, 1977.

The initial scope of the study effort was to review the issue of Federal versus State regulation of the commercial burial grounds. The scope of the study was expanded to include other related issues currently affecting commercial burial ground regulation and operation. These related issues included the need for research and development, development of a comprehensive set of standards and criteria for low-level waste disposal, development of a national plan for low-level waste disposal, and the need for adequate perpetual care funding. The Task Force Report reviews these issues, describes the present status of NRC and State regulatory roles in waste management, and presents conclusions and recommendations directed toward improving low-level waste management programs. The conclusions and recommendations of the Task Force are based on broad policy considerations and are not the result of a concern for safety of commercial disposal facilities as they are currently being operated. The Task Force recommendations are currently under consideration by NRC staff and Commissioners.

Conclusions and Recommendations - The conclusions and rationale that lead the Task Force to Recommendation I included responsibilities, resources, and national planning. The task Force found that the present system for low-level radioactive waste lacks national organization and direction. The States, through their regulatory programs have adequately protected the public health and safety. However, waste disposal is a national problem, and the States have neither the resources nor responsibility to develop and implement a national low-level waste disposal program. The development and implementation of such a program can be more readily and consistently achieved if the NRC assumes regulatory control and the Federal government assumes responsibility for perpetual care through Federal ownership of the land. However, the States will continue to have a vested interest in the protection of the health and safety of their citizens and in land use decisions.

From these findings, the Task Force made the following recommendations:

> Recommendation I: The NRC should initiate action, in cooperation with appropriate Federal and State agencies, to increase Federal control over the disposal of low-level waste by:
>
> A. Requiring
>
> (1) Joint Federal/State approval of new disposal sites;
>
> (2) NRC licensing, with State participation, of current and new disposal sites; and
>
> (3) Federal ownership of land for all disposal sites.
>
> B. Estabishing a federally administered perpetual care program.

The Task Force found that some standards and criteria have been developed for shallow land burial. Additional guidelines, which for the most part are site specific, were developed through regulation of the commercial site. A comprehensive set of standards and criteria based on national requirements covering all aspects of burial ground operation is lacking. Such standards that can withstand technical and public review should be developed. The Task Force further suggested that emphasis should be placed on:

1. Developing operating, monitoring, decommmissioning, post-operational maintenance, and funding requirements for both existing and future burial sites;
2. Developing criteria for the acceptability of future proposed shallow land burial sites or alternative disposal methods; and
3. Developing criteria for determining which waste can be disposed of by shallow land burial.

From these findings the Task Force made the following recommendation:

> Recommendation II: The NRC, in cooperation with appropriate Federal and State agencies, should accelerate development of the regulatory program for the disposal of low-level waste which includes regulation, standards, and criteria.

The Task Force also made a number of findings concerning proliferation of sites and alternative disposal methods. The Task Force found that while there have been other disposal methods used, the only currently practiced method is shallow land burial. Since the enactment of the National Environmental Policy Act (NEPA) a comprehensive Federal examination of alternative disposal methods has not been made. The Task Force also found that there is now sufficient burial capacity for the disposal of commercial low-level waste to the year 1990, based on the numerical capacity alone, not regional distribution. the Task Force therefore felt that there is sufficient time to develop, in an orderly fashion, a national low-level waste management plan, a regulatory program, and evaluate alternative methods of disposal before additional disposal sites need to be developed.

From these findings and beliefs, the Task Force made the following recommendation:

> Recommendation III: The NRC should initiate immediately the necessary studies to identify and evaluate the relative safety impacts of alternative low-level waste disposal methods. No new disposal sites should be licensed until a full examination of alternative disposal methods has been completed or unless an urgent new need is identified. The NRC should assure effective use of existing commercial burial grounds consistent with protection of environmental and social values.

Comments - The official comment period for NUREG-0217 ended May 9, 1977, but late comments are being considered. To date, the only areas of agreement were the need for national planning and development of comprehensive standards and criteria for low-level waste management and that the States must have a meaningful role in whatever direction we proceed. Views on increased Federal control varied. Some have no objection; others are opposed to increased control. Most recognized the national character of the problem, that coordination and planning are needed at the Federal level, and that a strong Federal role in long-term care and financing is indicated. The States are concerned about having an equal voice and about infringement on State responsibilities.

Views on Recommendation III included a belief that additional capacity for low-level waste disposal is needed in the East.

Comments from ERDA included a belief that additional options should be considered before Recommendation I is implemented and that the capacity and projections related to Recommendation III are overly optimistic. The ACRS generally concurred in the conclusions, but had reservations about long-term safety, exclusive national aspects, the scope of the Task Force's review, and the advisability of implementing Recommendation I at the present time.

Remaining Issues - The Federal/State Task Force Report raised a number of issues to be addressed in NRC's low-level waste management program. Briefly, the technical issues include those identified earlier resulting from the Table S-3 efforts plus the additional need for projections of low-level waste disposal capacity and economic analysis on a national and regional basis. The financial issues of performance bonding or equivalent measures and adequate provisions for long-term care remain; i.e., how to best assure that the waste originators and site operators meet their financial responsibility for safe disposal. Finally, the regulatory issues inherent in the Task Force recommendations concerning an increased Federal control must be addressed.

NRC PROGRAM DEVELOPMENT

Our implementation plan to structure a comprehensive low-level waste management program will address these issues and will include a number of aspects such as:

1. Data base studies;
2. Environmental impact statements;
3. Regulatory framework;
4. Coordination with Federal/State agencies; and
5. Input and participation from all sectors.

Data base studies will provide necessary information for input into environmental impact statements, assessment of waste management plans, and development of standards and criteria. Studies are under way and planned that address overall program issues and that address unique low-level waste considerations.

For example, criteria are being developed to classify waste according to the degree of confinement necessary to allow for decay to some acceptable level. Acceptable risk criteria and methods of application to management of all wastes are also being developed. Other studies are underway which are directly related to low-level waste program efforts. For example, a contractor is studying the properities and interactions of LWR wastes, solidification matrices, and packaging. A separate study of nonfuel cycle radioactive waste from educational and medical facilities is focusing on characterizing waste, waste treatment, and disposal methods.

Several additional studies are planned, but not yet contracted and funded. For example, a comprehensive review of alternatives to shallow land burial will compile possible alternatives and identify viable alternatives. A waste projection study is also being developed that will identify sensitive parameters, develop methods for assessing the chemical hazards and designing chemical monitoring programs.

A series of environmental impact statements will be required to support regulations and standards efforts. The exact number and scope have not been determined as yet. The environmental impact statements will serve as a forum for presenting the rationale for various decisions including, but not limited to, environmental considerations. In addition, legislation to expand existing authority may be necessary depending on the degree of Federal control pursued in the final program plan.

The waste management regulatory framework, and the low-level waste management framework in particular, to be logical, practical, and balanced must be a cooperative effort. Government agencies will have to work together to coordinate studies, develop standards, and exchange technologies and findings. Input from industry, the public, and Government agencies, both as groups and individuals, is vital. The importance of comments on published material such as proposed rules, and draft guides, reports, and environmental impact statements, and participation in workshops and meetings such as this one cannot be overemphasized. We would appreciate your input and your cooperation.

SUMMARY

In summary, we would like to highlight the following points of today's overview of the emerging NRC low-level waste management program:

1. Hydrogeological modeling and operational experience to date indicates no health and safety problems in the near term from operation of shallow land burial facilities, but our analyses continue;

2. The environmental impacts from shallow land burial are small and, when properly done, shallow land burial is an acceptable method of disposal;

3. An aggressive program to develop and implement comprehensive standards, criteria, and guidelines and review alternatives is indicated and is being pursued by the NRC and others (ERDA, EPA, USGS, the States, and industry); and

4. Specific programs and time tables are being formualted and should be available for comments soon. Input from all sectors is solicited.

We appreciate this opportunity to discuss our program with you, and anticipate fruitful exchange of views on a personal basis.

DISCUSSION

MR. JOHNSON: We studied your Task Force report quite seriously with the Western State Nuclear Board Waste Management Commission. You have probably seen our comments; they are rather long and voluminous. The recurring concept is where the NRC says, "We do not have a case where the health and safety of the public has been endangered by this State regulation." It is mentioned several times throughout the report. Then you turn right around in the next paragraph and say, "However, the Feds are still going to take it over," or they still think we have to for some reason or other. It is not made very clear.

In your future deliberations on the Task Force, or in NRC considerations, that would probably give them back to you if there is a good reason, but you have got to show us what the reason is. That is the general attitude that we have.

MR. ADAM: I can assure you, first of all, that there are many other groups that share your viewpoints. First, I would like to make a clarification on the finding of the Task Force and subsequent findings by the NRC. When we say that there is no public health and safety concern, first of all, that is said for at this time. We have not gone as far as to say there never would be. Future corrective actions may need to be taken in some cases.

The second point that I think we sort have been taken over the coals on, is the fact that when we make that statement, it is based more on the 10 CFR 20 type concept of public health and safety. Many groups bring up the question, "Is part 20 an adequate standard from which to judge the satisfactory performance of the disposal method?" I think in general we have to concede that it is not, and for no other reason than that part was never designed for that purpose. So, when we make the statement "there is no public health and safety...," all that statement has essentially said is that we have found nothing that forces us to take action at this time.

As far as the other considerations you brought up, the staff is well aware of these concerns. I would like to be able to sit down and discuss in detail just what the thinking of the staff is at this time; however, I think it is only fair that we present our talks to the Commission before we provide it to the public in general.

Our staff position should be in front of the Commission within a few weeks if it is on schedule. However, I would say because of the complexity in trying to resolve this particular issue, I doubt it will be on schedule.

MR. JOHNSON: Do you have a deadline?

MR. ADAM: Our deadline was July 7. I frankly do not know if we are going to be able to meet it, since the way we structure the rest of our program depends upon the amount of control that we recommend having, and that issue itself has not been fully resolved.
(NOTE: In October 1977, the NRC published NUREG-0217 supplement 1, "NRC Task Force Report on Review of the Federal/State Program for Regulation of Commercial Low-Level Radioactive Waste Burial Grounds - Analysis of Public Comments," and NUREG-0240, "The Nuclear Regulatory Commission Low-Level Radioactive Waste Management Program." The FEDERAL REGISTER Notice giving the statement of Commission Policy on this issue was published on December 8, 1977.)

MR. WOLLE: I, for one, do not have much problem with the Federal or national. I think that maybe it is the best approach. However, I would like to ask you what you mean in your Task Force report when you talk about State participation in deciding and licensing facilities. You talk about monitoring, but you don't want monitoring. What do you determine that the State can say as to the criteria on effluent releases? And let us get away from this business of the Federal siting, and of meeting not a State permit or the State license, but meeting State standards itself when, in fact, they rarely ever do.

If there is some way that you can assure the States that they will be a party to the licensing and a party to the criteria, to the extent that they will have something to say about meeting the standards in lieu of State licensing, and then I do not think you will have a problem.

MR. ADAM: I think you touched on what comes down to the central problem in trying to come up with a detailed program for joint Federal/State participation in low-level waste management. The Task Force had the luxury to indicate which directions they thought we should go. If it were just a matter that Federal Government is going to take over shallow land burial, the question would be easy, and the question of how this would be accomplished from a criteria standpoint and so forth would be relatively easy.

Now, we are concerned about the States' vested interest, and we are trying to develop a mechanism for State participation that is workable. Protecting the States' vested interest, as you have identified, is not easy.

MR. WOLLE: It is not. It has not been accomplished in the past and that is where the problem is in the States. They always say we will meet the State standards and such, but we do not have to. Now, if you will establish some mechanism in this that they will have to, then I think we will have no problems.

MR. ADAM: That is one of the things that we are trying to do right now, is to see if we can develop a mechanism where this would be accomplished.

STATE EXPERIENCE WITH WASTE BURIAL SITES AND THEIR RESPONSE TO NRC's TASK FORCE REPORT

Frederick S. Adair
Washington Energy Office
Representative to the Western
Interstate Nuclear Board

Charles M. Hardin
Radiation Control Branch
Kentucky Department of
Human Resources

Heyward G. Shealy
Bureau of Radiological Health
South Carolina Department of Health
Health and Environmental Control

James A. Blackburn
Radioactive Materials Licensing
Illinois Department of Public Health

MR. ADAIR: How did Washington become involved with a low-level waste disposal site? For the answer, let's look at history. There are a number of factors.

In the late 1950's and early 1960's, Federal nuclear activity at Hanford was on a marked decline. Rather than see a ghost town develop, the Tri-Cities Community, aided by the State Government, set about to bring in commercial nuclear business. Today we see a large non-Federal fraction in the Tri-Cities economic base and employment levels back to what they were over 20 years ago. The community, of course, deserves the lion's share of credit for this success.

One element essential to nuclear activity is a disposal site for low-level waste. This need, together with the Atomic Energy Commission's policy that this activity should be commercial rather than government, made development of such a site at Hanford a natural.

As a business promotional step, the State leased in 1964, for 99 years, 1000 acres on the Hanford Reservation, on the condition set by the Commission that business use be nuclear or nuclear-related. The State then subleased 100 acres to California Nuclear in 1965 for use as a low-level waste disposal facility. The term of the sublease is for 10 years with two 15-year extension options at the discretion of the sublessee. The sublease was transferred to Nuclear Engineering Company in 1968 and NECo exercised tne first of the two extension options.

During extension negotiations, the State investigated the issue of bonding. Recognizing that bonding fees must compete with growth in the perpetual maintenance fund within a given dollar spread, careful study was in order. It was concluded that maximum growth in the perpetual maintenance fund is indicated at this time and that bonding should not be required. it is stressed that this conclusion applies to this particular site at this point in time. Circumstances can change and call for reassessment of the issue. However, today the site is located on a limited access Federal Reservation, juxtaposed between two high-level sites, justifying the aforementioned conclusion.

A recent and still pending problem is disposal of transuranic waste. This site is the only commercial site now receiving TRU waste. ERDA requested that interim, retrievable storage be implemented in place of permanent disposal. The State and NECo set about to establish procedures acceptable to ERDA and this is almost done, but there remain to be resolved some important financial issues. Once buried, the waste is disposed. If some is to be exhumed, this is a new enterprise and the instigator would have to fund it. However, interim storage has the obvious commitment to some future action, as yet unspecified, and for that matter, unknown. No funds are available for this. NECo, the State, and ERDA have negotiated over this issue for some time, culminating in a productive session last December. At the staff level, ERDA agreed to produce quantitative basis for a surcharge together with a guarantee beyond a set figure. This concept, satisfactory to NECo and the State, remains to be approved at ERDA headquarters. Another issue is potential impact on the NRC license. With the former disposal method, material was "held" only while being processed enroute to burial. Once buried it was no longer "held." Will the material in interim, retrievable storage be "held"? If so, the NRC license will require modification.

From several directions we see a growing probability that the Federal Government will assert jurisdiction over this site. We have given the matter a lot of thought and concluded, on balance, that we are rather indifferent or even a little disposed to have the Federal Government assert jurisdiction. In any event, we will continue to monitor the site, but transfer to the Federal Government would pass a number of problems to which only the Federal Government has the answers--notably the aforementioned financial issue. Businesses generally prefer to do business with the State and, with State control of licenses (NECo has a license with the State as well as with NRC), the State is better able to ensure compliance with regulations. On the other hand, this is only one license and the future seems to indicate ever-increasing management time requirements. Thus, the balance seems to tip toward Federal control.

MR. HARDIN: The land on which the site is located is owned by the Commonwealth of Kentucky and leased to the operating company. The lease agreement is administered by the Kentucky Executive Department for Finance and Administration.

The first disposal of waste occurred in May 1963. A total of 2,225,016 curies of byproduct material, 532,675 pounds of source material, and 413,855 grams of special nuclear material has been buried as of April 1, 1977. This amount of radioactive material was contained in 4,767,556 cubic feet of waste.

The license only authorizes the disposal of solid radioactive waste. Originally, the license provided for the operator to receive low-level radioactive liquids. These liquids were solidified using cement and paper. The solidified waste was then buried in specially designed trenches lined with plastic. In 1972, the license was amended to restrict the further receipt of low-level liquids.

Prior to 1974, the license authorized the burial of transuranics. An amendment in 1974 restricted the burial of transuranics to a concentration of 10 nanocuries per gram. There presently are no restrictions on the concentration of other radioactive waste nor on the half-life of the waste.

Once the facility is closed, there will be a requirement for long-term care of the site. This long-term care will require:

1. Trench Maintenance - Due to voids in completed trenches, caps will subside resulting in the breaking of cap integrity. Recapping procedures will have to be performed.
2. Trench Water Removal - As indicated earlier, water infiltration does occur, regardless of the good capping efforts that are made. Therefore, the constant removal of water from trenches will be required to assure that a hydrologic head does not exist, and also that the "bath tub" effect will not occur. Connected with this water removal is the more costly problem of water volume reduction and/or solidification.
3. Fence Maintenance - A fence must be maintained for proper security at the site.

In 1972, slight elevations were found in certain sampling stations in the immediate environment surrounding the site. Intensified monitoring indicated that the elevated radioactivity was manmade nuclides which had to originate from site operations. Although the levels of radioactivity in the environment have never represented a public health hazard, the levels were above background.

As a result of improper management prior to 1972, water accumulated in certain trenches. Because of certain regulatory actions and, in particular, a change in management of the site, an intensive water removal program was initiated. This program includes the reduction of the water volume removed from the trenches through evaporation. Solidification was considered as an option, but because of the cost of solidification, and more importantly, because of the absence of any criteria for what constitutes an acceptable solidified liquid for shallow land burial, evaporation was considered as the best option for water volume reduction.

This evaporator is designed to remove all radionuclides with the exception of tritium. The restrictions of operation are therefore based on the rate of release of tritium. The allowable release rate of tritium is based on one-tenth of MPC's at the nearest residence, and in actual practice, the tritium levels in the environment are only a fraction of this allowable limit.

It would appear from our experiences with the Maxey Flats disposal site that the burial of radioactive waste in certain shallow land geological formations is an aceptable method of disposal. However, for this method to be acceptable, a uniform national criteria must be established as to what is "acceptable."

I believe, as a minimum, national criteria are needed in the following areas:

1. Acceptable release rates from shallow land burial sites.
2. Categorization of "other than high-level waste."
3. Types of scientific studies required to determine the acceptability of geographic areas for siting of such disposal facilities.
4. Standards for acceptable solidified liquids for shallow land burial.
5. Standards for acceptable environmental monitoring programs.
6. Standards for adequate financial coverage to the landowner in areas of (a) Long-Term Care and (b) Bonding.
7. Standards for decommissioning of established sites.

In discussing the criteria recommendations, one very basic criteria, at the national level, must be addressed. The question must be answered, with the assumption that shallow land burial is an acceptable method for radioative waste disposal, should there be a proliferation of such sites. Should each State have such a site, or should such sites be on a regional basis? If on a regional basis, should such sites be the responsibility of a State in which it is located, or the responsibility of the Federal Government?

It is my opinion that the best approach to the above questions, since I firmly believe that the disposal of radioactive waste by shallow land burial is an acceptable method, when the site is properly chosen, and the burial properly managed, is to establish regional sites which are the primary responsibility of the Federal Government. This is not to indicate that the State in which such a site might be located has no "say" in its proper location, and in the regulation of the operation of the site. State regulatory and environmental agencies should be a full partner with the Federal Government determining the acceptability of such a site and the manner in which it is operated.

The first recommended item for national criteria was acceptable release rates. A standard must be established as to what is acceptable release rates. A standard must be established as to what is an acceptable release rate for such sites. ALAP or ALARA must always be applied, but for the regulator, these nonquantified terms are difficult to deal with. Therefore, an acceptable release rate in quantified terms is needed for proper regulation.

The second recommended item relates to the categorization of "other than high-level waste." You have noticed that I have purposely ignored the term "low-level" waste, since I do not believe that such a broad term is appropriate for the kind of waste we are discussing. I believe that "other than high-level" waste could be categorized into "intermediate-level" and "low-level" waste. For discussion purposes I suggest the following for consideration of categorization:

Intermediate-Level: All treated waste (e.g., solidified or ion exchange resins), high specific activitty waste (e.g., 1 curie per cubic feet or greater), and long half-life waste (30 years or greater).

Low-Level: All other waste, with the exception of waste resulting from disturbing of earth, such as mill tailings which will not fall into the above category.

The intent of such categorization is to apply different burial methods to the two categories. In practice, probably 90 to 95 percent of "other than high-level waste" will fall into the low-level category. Such waste is generally high in organic material which can complex radioactive ions into a soluble and more mobile form. If the two categories were buried separately, the highly complexing material would not be in contact with the higher activity material in the intermediate-level category. Also the smaller volume intermediate-level waste could more easily be retrieved if so desired.

Much research has gone into acceptable agents for solidifying high-level radioactive liquids. Some of these agents may also be acceptable for shallow land burial. However, a completely different standard may be required for shallow land burial when compared to deep burial of high-level waste. I strongly recommend the development of a national standard as to what is an acceptable solidifying agent for shallow land disposal, as soon as possible.

Although the burial of radioactive waste into shallow land sites has come under a great deal of criticism, the experience at the Maxey Flats site in Kentucky indicates that this method of burial can be performed in an acceptable manner. This acceptable manner may require the categorization of "other than high-level waste," and these different categories handled differently. Other considerations must be given to standards for solidification of liquids, and other water management programs. Most importantly, the landowners of such sites must be provided with adequate financial coverage for long-term care after the site is closed and decommissioned.

MR. SHEALY: The State of South Carolina became involved in the regulation of ionizing radiation in 1967 when the South Carolina Legislature enacted the Atomic Energy and Radiation Control act. On September 15, 1969, the State became an "Agreement State" pursuant to Section 274 of the Atomic Energy Act of 1954 as amended, thereby assuming regulatory responsibilities for certain radioactive materials. Such responsibility includes the licensing of low-level waste burial facilities; and, on April 13, 1971, one such license was issued to Chem-Nuclear Systems, Inc., authorizing the use of approximately 250 acres of property in Barnwell County, South Carolina. However, as early as 1950, South Carolina was the site of nuclear facilities at the Savannah River Plant in Aiken, South Carolina, where much radioactive waste, including high-level waste, has been generated and is presently stored. From these factors, one can easily ascertain that our State is concerned about the role of States in protecting their citizens and environment from the hazards of nuclear waste.

Presently, nuclear power reactors supply approximately 9.0 percent of our Nation's electrical power generation. In the State of South Carolina greater than 40 percent of the State's power generation is from nuclear power reactors. For the short-term future, our reliance upon nuclear power will certainly increase. An inherent product of such operations is radioactive waste that includes the mill tailings, depleted uranium from the enrichment process, reactor generated waste such as spent resins, and solidified low specific activity waste, and various forms of contaminated materials, equipment, and so forth, associated with the various states of the nuclear fuel cycle.

The six commercial sites handling large quantities of radioactive waste are licensed to handle byproduct, source, and special nuclear material. All commercial sites, except Sheffield, are located in Agreement States and are regulated by such States. At Beatty, Hanford, and Barnwell, the NRC licenses special nuclear material because of quantities exceeding Agreement State jurisdiction. Sheffield is regulated by NRC. All sites, except

Hanford, are located on State-owned property. Hanford is located on Federal lands leased to the State of Washington.

Since South Carolina began commercial land burial of radioactive wastes, over 4 million cubic feet have been buried at the Chem-Nuclear burial facility located near Barnwell, South Carolina. By the year 2000, the U.S. Environmental Proteciton Agency estimates that approximately 1 billion cubic feet of radioactive waste will have been generated. EPA also estimated that the six existing sites will be filled to capacity by 1998.

Regulatory responsibility for radioactive waste is primarily that of the NRC or the Agreement State having jurisdiction over the licensee possessing such wastes. As licensor, many States regulating commercial burial facilities and/or uranium ore processing mills thus have substantial roles in radioactive waste disposal. Most States also have some legislation assigning to one or more of its regulatory agencies the responsibility of protecting its citizens' health and safety and its environment from the hazards of nuclear wastes to the extent this responsibility is not federally preempted by the Atomic Energy Act. These responsibilities equate to a minimization of radiation exposure from such wastes during their generation, packaging, transport, and disposal. Ensuring compliance with applicable regulations can generally accomplish this, although inadequacies in current regulatory programs have been identified. Beginning in 1971, the National Conference of Radiation Control Program Directors' Task Force on Radioactive Waste Management identified many of the regulatory and operational inadequacies with respect to low-level radioactive waste management. Similar areas of concern appeared in the U.S. General Accounting Office Report entitled "Improvements Needed in Land Disposal of Radioactive Wastes -- A Problem of Centuries." A House of Representatives Subcommittee on Government Operations held hearings during February, March, and April of 1976. In addition to representatives from five Federal agencies and one commercial burial ground operator, the States of Illinois, South Carolina, and Nevada presented testimony before this Committee.

The State of South Carolina recognizes the deficiencies identified in the report on radioactive waste disposal prepared by the General Accounting Office, and concurs in many of its recommendations. Specifically, we can agree that systematic site selection criteria should be established, that standards for radionuclide migration in soils may be beneficial, that more stringent regulations can improve disposal site operations, that more attention needs to be given to long-term care requirements and funding arrangements, and that Federal policy regarding corrective actions may be needed. However, we cannot agree that the "Agreement States" as a whole are unable to regulate low-level burial facilities.

Our actions have been responsible and responsive in the content of existing regulations, regulatory policy, and public needs. Should changes be made in the regulation of low-level waste burial facilities, then our only comment would be that the "Agreement States" should be given the opportunity to demonstrate their continued responsible regulation of burial sites. A more responsible approach to regulating burial sites has not been demonstrated by Federal agencies, and we believe that we can operate effectively in a changed regulatory environment.

The responsibilities of the States regarding the regulation of radioactive wastes may become less in the near future. In a report, "Low-Level Nuclear Waste Disposal" (House Report No. 94-1320), the House Government Operation Committee recommended that the Federal Government move rapidly to develop a coordinated program for the safe management of low-level radioactive waste and consider assertion of Federal Control over regulation and ownership of the commercial burial grounds. These actions appear to be in response to the growing concern regarding radioactive wastes and the recognition that the disposal sites of such wastes serve or have generally served national rather than state interests.

The NRC "Low Level Waste Disposal Task Force Report" FEDERAL REGISTER, Volume 42, No. 47, concluded that because current Agreement State regulatory programs were adequate to ensure public health and safety, the NRC had no authority to assert Federal control over regulations and ownership of commercial burial sites without changes in the Atomic Energy Act. Nevertheless, the Task Force recommended the following:

1. Requiring joint Federal/State approval of new disposal sites;
2. Requiring NRC licensing, with State participation of current and new disposal sites;
3. Requiring Federal ownership of land for all disposal sites;
4. Establishing a Federally administered perpetual care program;
5. Further development of the waste disposal regulatory program; and
6. Immediate studies to evaluae the relative safety and impacts of alternative low-level waste disposal methods.

Should State regulatory responsibility be reasserted by the Federal Government in the aforementioned areas, this does not equate to a reduced State role. States should continue to provide emergency response capabilities for accidents involving such wastes and independent monitoring of exposures and effluents from such wastes. Such activities should increase in proportion to increased waste generation. The role of States in the selection of disposal sites should increase in future years. Although it is anticipated that additional low-level burial sites will not be needed through the 1990's, the Federal Government is pursuing several studies pertaining to high-level waste disposal site selection. The States should take an affirmative role in ultimate site selection and disposal methods and ensure that optimum treatment is afforded such wastes.

In conclusion, I would emphasize that our commitment to nuclear power in the near future will result in the generation of radioactive waste that will require appropriate disposal. The benefits of this nuclear industry occur to our Nation as a whole. therefore, it is necessary that our States assume a responsible position in the disposal of nuclear wastes. Such position requires that disposal sites and methods be selected that optimize treatment of these wastes.

MR. BLACKBURN: My remarks must be considered as my personal observations and not necessarily those of the Illinois Department of Public Health. I would like to informally discuss the Sheffield Nuclear Waste Disposal Site as I view it at this time. This perspective may be colored by the fact that I have just recently assumed responsibility for its operation (April 1, 1977), and as of yet am still attempting to orient myself to the waste management arena. The second major item I would like to address is purely hypothetical--it is an answer to the unasked, but often thought of question; if you were going to state a radioactive site today, what would you do the same? What would you do differently?

First let us consider reality. The Sheffield Nuclear Waste Disposal Site was first made possible in 1963 when the Illinois General Assembly approved the Radioactive Waste Act. This Act enabled the Department of Public Health to accept title to property for the purpose of establishing a radioactive waste disposal site. Following this legislation, the Department drafted a "criteria" that was published in March 1965. Proposals were solicited with the eventual result being the purchase of 67 acres of land in northwest Illinois by California Nuclear. Approximately 20 acres of this site was then deeded over to the State. The site location and size has remained constant since that time. (In 1968, California Nuclear sold its interests in the operations to Nuclear Engineering, the present contractor.)

The criteria for the site as established in 1965 and as utilized today contains two criteria that are the foundation of the State's program in low-level radioactive waste management. One of these criteria is not unique - we require that only solid waste be buried at the site. Although liquid may be received, it must be solidified prior to burial. At the present time we have no written definition as to what is a solid; however, we do insist that all shipments be free of standing liquids and that the liquids be fixed into the solid matrix rather than absorbed into a substance such as vermiculite or sawdust.

The second criteria established by the Department has been mentioned several times this week and certainly is unique. This criteria excludes from the site all waste containing more than 1 curie per cubic foot. This criteria was established simply to insure that the site would remain a low-level site. Since the State is required to assume perpetual responsibility for the site, the staff deemed it desirable to place a limit on its liability in this regard. There have been a few instances in the past where specific shipments that exceeded this limit have been accepted by the Department for burial. These shipments, however, have contained relatively short-lived nuclides and have been accepted on an individual basis. (It should also be stated that several requests for such exemptions have been denied because of the same rationale.)

A second aspect of the Sheffield Nuclear Waste Disposal Site that is unique is its licensing arrangement. Since Illinois is a nonagreement, licensing State, the site is required to possess two licenses; one from the NRC authorizing possession of byproduct, source, and special nuclear material, and one from the State similarly authorizing possession of naturally occurring and accelerator-produced radioactive materials. Although other people may dispute the point; I personally believe that such an arrangement gives the State the best possible site. I certainly do not claim to have the expertise that the NRC can assemble to review the technical documents required for such a site. As such, I am content to allow the NRC to assume the lead role in licensing such a site. Since Illinois is a licensing State, however, we are able to ask any questions that seem pertinent to us in this regard. In addition to our licensing function we have the concern and responsibility that is assumed with ownership of the site. We are much closer to the site than Washington. In true health physics fashion, what to Washington may appear to be a point source, to Springfield, may appear to be much larger.

The third aspect of the site that I would like to discuss is the environmental surveillance that is conducted by the State. The original concept of monitoring was to establish several wells around the site boundary and monitor their water for migrating radionuclides. In the present political climate, however, such a program in itself is insufficient. With the assistance of the USGS, we have drilled several wells in the last year to expand this effort. Such a flurry of activity, however, can lead to a perception of difficulty at the site. (If there is not a problem, why all the activity?) Although dismayed b, this response, I can understand it. If I were to view 10 policeman congregating at a particular location, would I not accept the response that nothing was going on.

The last aspect of the present program that I believe needs to be discussed is the necessity for the State regulatory agency to maintain a neutral position in all action taken by others regarding the site. At the recent zoning hearings, the State was called by the contractor as a witness in the case. This action again gave the perceived appearance that the State was in fact attempting to influence the decision. As a consequence, I believe that our reputation and data became suspect and lost its credibility.

Let us move now to the hypothetical aspects of starting over. What changes would I recommend? Very briefly let me mention four areas of concern that needs further study and possible change. these items include:

1. Land Acquisition: At the present time, only the land actually being used for the basic operation is deeded to the State. This enables waste to be buried to the very edge of the State owned land. We have required that a 200-foot buffer zone be established around the site, however, this land is not owned by the State. Should it be sold, the State would be placed in an awkward position of having waste buried in justaposition to private land.

I believe that as a minimum the burial site itself and the buffer zone need to be owned by the State. More desirable would be the entire site. Such a policy of land acquisition would also protect the State in case of premature closing before the perpetual care fund was fully established.

2. Environmental Surveillance: I have already mentioned the perceived reason for extensive enlargement of the sampling program after the site has been operating for several years. A solution to this situation would be the orderly sinking of a monitoring well as the site is filled. For example, following the closure of a trench, a well could be drilled at each end and along one side as established by the site criteria (for example, one well for each 200 linear feet of trench).

3. Funding: The present rate of funding coming to the State as a result of the operation of the site is 10 cents per cubic foot (as of January 1977). Assuming a rate of burial equal to 1976, this will give the State less than $50,000 to fund its present activities at the site as well as provide for perpetual care of the site. Since the present level of spending is almost this amount, it is clear that the users of the site do not totally pay for the governmental service connected with it. I personally do not believe that the citizens of Illinois should subsidize the citizens of Minnesota, Michigan, and Pennsylvania by taxing themselves to care for out-of-State waste. My approach to this problem would be to fund the State operations for the site from monies collected by the site on the waste buried. This would mean that the fund would need to be of sufficient size to allow the operational costs to be removed on a annual basis without depleting the fund such that the interest from the fund would be sufficient to pay for the perpetual care eventually needed at the site.

4. Solidification: Regarding the solidification of waste, I have no solutions, only a statement of the problem. Our contractor is frequently faced with the problem of free standing liquids inside the container. This places them, and us, in a situation with no easy solution. The desirable solution would be to refuse to accept the material and return it to the originating shipper. Since the package was not designed for liquids, however, this is in direct violation of transportation regulations. The only recourse that is left is for the site operator to solidify the liquids in the best possible manner before burial and charge the additional expense to the original shipper. A second action that is being contemplated by the State of Illinois is for us to also issue a formal citation against the shippers because of the violations in the transportation of such shipments.

The last item I wish to discuss is an area that I believe is about the only area that has received less attention than the burial of low-level wastes. This item is the transportation of these low-level wastes from the nuclear power facilities to the burial sites. Since the beginning of 1977, we have discovered over 100 instances of misclassification, and improper packaging as well as incomplete documentation. The most glaring problem at this time appears to be in the use of LSA (Low Specific Activity) wastes. The majority of the waste from the reactors are a complex mixture of activation products, corrosion products and mixed fission products. Only the latter is an acceptable proper shipping name. Because of the presence of Sr-90 in the material, however, MFP must be shipped as Transport Group II. This limits the specific activity of MFP to 5 microcuries per gram if the LSA criteria is to be used. Since LSA is exempt from specification packaging by USDOT regulations, it is economically advantageous to use this criteria if at all possible. If, however, the material could be shipped as Transport Group III, the LSA criteria allows 300 uCi per gram. We have discovered that some facilities have simply elected to list the major isotopes (Cs-137 and Co-60) and then proceed to ship the material as Transport Group III. Other facilities have listed the material as MFP yet have consistently exceeded the LSA criteria. Neither case is proper. As I interpret the USDOT regulations, the only possible (legal) solution would be to either do a complete isotopic analysis on each shipment (including strontium) or ship the material as MFP using the more restrictive Group II levels. Such a solution would limit the activity in a 55-gallon drum, weighing approximately 650 pounds to 1.48 curies. This is far less than the present usage. Such a solution also runs at cross purposes with the volume reduction we have heard about this week. Exceeding this activity, however, results in a Type B shipment requiring the accident-proof containers for shipment.

The NRC is even more strict in their interpretation of 10 CFR 71. As I interpret their statements, even LSA must be shipped as either Type A or Type B. If this is true, all shipments of MFP that exceed 50 millicuries and all shipments of cobalt-60 and cesium-137 that exceed 3 curies require Type B containers. Our experience indicates that this simply is not being done. Yet who is enforcing these regulations? Let me state that Illinois will be very soon. We have recently obtained some equipment from the USNRC that is being installed in several State police cars. These Troopers have all received a minimum of 96 hours of civil defense training. This has been followed with a 3-day session on the nuclear fuel cycle. Two weeks ago, we again had them together for 2 days devoted to the transportation regulations. The equipment issued to the State Police has been shown to be capable of detecting less than 1 mCi of cobalt-60 at 35 feet from the road when passed by the trooper at 55 miles per hour. We are not planning on painting parking strips in the bottom of our burial trenches for impounded trucks, however, we are discussing and will be drafting "out of service" criteria for those violations of such severity that an eminent health hazard could exist.

I want to explain that our concern in this area is for us all. Should one of these trucks be involved in a severe transportation accident and somehow a drum break loose, all of us would instantly feel the political repercussions. Those in the industry would be castigated for not following the regulations. We, as regulators, for not forcing compliance. Let's comply with the transportaiton regulations, today, before the accident happens. It can only make life easier for all of us.

DISCUSSION

MR. CASHMAN: With regard to the study that was made on the releases from the State licensed burial site, I think it would be helpful if there were specific comparisons made with releases from the federally operated site. Secondly, the comment that you made in regard to saying you feel the same, there would be no health and safety problems at this time. You indicated you were comparing this with the Part 20 limits, when you use Part 20, you begin to think of the terms 500 millirems.

Now, the EPA report on the releases from the nuclear field servicing site regulated by DOC, State of New York, indicate that the maximum exposure for the releases that did occur through the planned pumping and release of treated water was less than 0.01 millirems. I think the implication was that might have been as high as 500 and just under 500 and, therefore, "I seem to find that acceptable," is a wrong impression of what was actually released from the site. I think the same may be true in Kentucky. The actual releases were very low, far below Part 20 limits.

MR. ADAM: I would like to cover the last part first. When I made the reference to the Part 20 limit, that, true, was a criterion that was used. You are correct in stating that offsite doses did not come near, in a very general sense, the Part 20 limits. It becomes a little more interesting if you start looking at the MPC values.

In some cases, you will find instantaneous concentrations slightly exceeding the MPC values. However, the concentrations in Part 20 were not intended to be applied to releases from waste disposal. As we go before many groups, we get ourselves into trouble trying to use such a rationale. We are comfortable with the fact that there has not been a public health and safety problem, or we would not have stated it in the manner that we have.

With regard to releases from federally operated sites, there are several things that differentiate the ERDA sites from the commercial sites. I will not try to speak to the quality of the ERDA operations, only to say that from the time of inception, their basic principles to some extent were a little bit different. The fact that the site was co-located with a generating facility put some limitations on the site suitability, and the type of waste that went in; often the waste was chemical rather than radiological.

When all these things are put together, it is very difficult to compare the ERDA operation with the commerical operation without considering the waste origin. I think the point that you are trying to make is that the Federal Government has not demonstrated a greater capability than the Agreement States to manage low-level waste disposal. I do not think we are making the argument that we have, in fact, performed better. What we are saying is that we have now decided to act and that we have got the resources to do it.

The question is does the Agreement State have the resources to do it? We do not know the answer to that right now.

FROM THE FLOOR: I have two question for Jim Blackburn. One, has the State of Illinois taken action to put the 10 cents per cubic foot into other than the general fund as is the case in all the other States? Two, I understand the State legislature is considering a bill which would prohibit the importation of waste into the State of Illinois?

MR. BLACKBURN: In answer to the first question, the answer is no. At the present time the State legislature does not like dedicated funds. When they changed the constitution in 1970, they specifically made it a constitutional requirement that there would be no dedicated funds; that everything went into the general revenue fund, either upon receipt or at the end of the fiscal year. (NOTE: On September 20, 1977, Public Act 80-838 was signed into law establishing the "Radioactive Waste Site Perpetual Care Fund." This fund is mandated to be of a size that will provide for all reasonable costs necessary to maintain, monitor, and otherwise supervise and care for the site on a continuing and perpetual basis.)

We are, at the present time, contemplating coming in next year with some legislation that would specifically authorize this one fund for this one purpose so that it would have a dedicated fund. But at the present time, no; the monies that come in would go to the general revenue, and so there is no fund for that purpose (see NOTE above).

The second question is the out-of-State waste. Yes; this is true. It was actually a spinoff of toxic chemical wastes. We have a toxic chemical waste site that has received much political publicity and attention from the Governor and the attorney general and the legislature because it was located right on the edge of a small town. In fact, part of it is inside the town limits. And they are burying such items as PCB's and everything else. Consequently, that has raised a real problem.

What the bill does, if it were enacted as it was written, would prohibit the transportation into the State for burial of any hazardous material. Since it was introduced too late to have the normal course through the legislature, it required an emergency 75-percent vote. And it failed because it only got 11 votes affirmative rather than the 12. It was 11 to 4, rather than 12 to 3. So, I think you realize that there is a fairly decent amount of support for the bill, but it did not at that point get through. This does not mean that it cannot be introduced again. They are still in session, and if they can get the required 75 percent, it will be reintroduced.

MR. O'BRIEN: I find that the States sound like they feel that they are meeting their obligations in waste disposal in terms of improving the waste sites. I wonder if there is not some nearsightedness in only seeing the final disposal as an aspect that the State can serve. What I am referring to is some of the statements referring to enforcing the DOT regulations and accepting only solidified liquids. Both of these become a very significant problem for the generator (the user), and costs the taxpayer either directly from companies, or in the case of the University of Washington, our costs for preparation of waste comes out of the taxpayer's pocket.

It seems that perhaps the disposal sites could also be a site for receiving liquid and preparing that liquid for final disposal. The dispoasl sites could also accept packages, where the packages themselves do not have to meet DOT regulations for burial, but might be removed from a DOT spec package and buried as such. Generally, it has been our experience that the only thing that we can bury is a DOT package that has to meet the regulations of transportation, but hardly needs to be that rigorous a package when it is placed in a trench.

MR. HARDIN: Let me try to answer in some of the ways that you have posed it.

First of all, I think I would concur that to improve the disposal of radioactive waste would ultimately put an additional cost on the generating industry, which in turn we know that citizens pay for. I don't doubt that. I think the concept that I recommended in my paper, that regionalization may be a thing to look at, would provide several good aspects, for example, you would be able to look at many different kinds and varieties of geological formations and ultimately find the best in a given region.

And conceptually, one might say that that facility that you would find, that would be the best, that you could provide an additional service in addition to the burial of waste. I do have problems, however, and I think Mr. Blackburn was alluding to that, of shipping radioactive liquids on the highways regardless of whether they are low-level activities or high-level activities, and personally think that the solidification of the waste should be done at the point of generation. If there is an accident, whether it be a real radiological health accident or not, I think the nature in politics and the emotion in radiation today would prohibit the transportation of radioactive liquids.

So, although conceptually and theoretically a good regional site could provide possibly more service than just the disposal of waste, I do not think it would be in the best interest to ship radioactive liquids on the highway.

EVIDENCE PREPARATION

Raymond Malecko
Food and Drug Administration, HEW

Many of you perhaps have never testified in a courtroom or in an administrative hearing, and probably many of you have never even given any thought to the preparation of evidence, the development of evidence, and the fact that you may have to testify.

I am sure most of you agree that it is all right for FBI agents or policemen to be concerned with evidence development and testifying, but not you. You may say, well, basically, I am a consultant. I do not deal with criminals. I deal with the understanding members of my community. Why should I be concerned with evidence development?

The truth of the matter is you are enforcing law; whether it be a Federal, State, or local law, you indeed are a law enforcement officer. You must remember that everything you do is subject to court review or to review during an administrative hearing. What is more, you may be called to testify many months or even years after your investigation, and we all know what can happen to our memories after that period of time.

I would like to give you some simple facts and simple rules on evidence preparation, that can be applied to anyone, no matter what type of a law you enforce.

I would also like to give you a little insight on how the Food and Drug Administration handles their evidence. We have had approximately 70 years experience in handling evidence, and what I may give to you may be of value in your work. I would suggest that when you get back home, you review what you have been doing and if anything I give you today can be applied to your work, you may want to consider it.

First of all, we have to define what is evidence. Very simply, evidence is information. In the legal sense, evidence is information that may be considered in the determination of a dispute during a hearing or in a court of law. It is a means sanctioned by law to determine the truth of issues in question. Evidence introduced at administrative hearings or at a trial are of two natures; (1) direct evidence and (2) circumstantial evidence.

Direct evidence is information that directly and immediately brings about a conclusion upon the issues. Circumstantial evidence, on the other hand, is information that does not relate directly to the issues, but relates directly to another set of facts which, once considered, relates to the issues.

Let me give you a little example. If a mother were to ask her child, "Did you take the money from my purse?" if he says, "Yes" or "No," that is direct evidence.

However, if she asks, "Did you buy anything today," this would be considered circumstantial evidence. The effect of circumstantial evidence depends upon the inferences that can be drawn from it, and the ultimate weight of the circumstantial evidence depends upon the inferences that can be drawn from it, and the ultimate weight of the circumstantial evidence rests with the judge, the jury, or the hearing officer.

Basically, evidence takes many forms, but I would like to limit our discussion today to physical evidence; the evidence that investigators normally are concerned with.

I would like to talk about diaries kept by investigators, reports prepared by investigators, documents copied by investigators, samples that may be collected by investigators, and photographs that may be taken by investigators.

Believe it or not, every investigator should maintain some kind of a diary. It is not very fashionable today to keep a diary if you are an investigator, and I think the reason why is, if you recall, I have never seen Kojak on television make any notes during his investigation. He is too busy eyeing the women. I have never seen McGarrett on Hawaii Five-O taking notes. I have never seen any of our investigators on television writing notes in diaries, and believe it or not, I know of some Federal agencies whose investigators do not maintain diaries. A diary can be very important. Your notes should be taken either during the investigation or as soon as possible thereafter. Do not rely on your memory.

Every investigator should realize that during a trial there is a good possibility that his diary may be turned over to the defense attorneys, and many irrelevant or thoughtless points placed in the diary may later come back haunting investigators. I would like to give you an example that happened to the Food and Drug Administration.

About 10 years ago, we had a cancer remedy on the market that was widely promoted as a cancer remedy; the FDA thought it was fraudulent, and we made an investigation.

The center figure in this investigation happens to be a Dr. Steven Derovick. A team of FDA investigators inspected his facility to get evidence that sooner or later may be used in the court of law. Dr. Derovick was European born and he had a very marked accent. He was a little hard to understand. One of the investigators wrote in his diary, "Dr. Derovick is very hard to understand." A couple of years later these investigators had to testify. They were on the witness stand, and every single time they tried to give their testimony concerning their conversations with Dr. Derovick, the defense attorneys jumped up and objected on the basis that the inspectors put in their diary that Dr. Derovick could not be understood. They tried to cast doubt upon the credibility of the investigators. This did not really materially hurt our case, however, it did help delay this case as the case went 9 months, and it did cause the investigators to be rather flustered on the witness stand.

One of the favorite ploys of defense attorneys is to attempt to fluster the Government witness. If he can do that, he can cast doubts of credibility as to his testimony.

Consequently, we should be very careful what we put in our diaries. Investigators normally write reports of what they do. If you watch television, you normally see the harrassed police officer or whatever at the end of the day writing his long report. They do it on Adam 12, and they do it on Barney Miller, they do it every place I have seen, so one must assume that investigators write reports, but that is not true.

I was recently involved in a case involving another Government agency and we were preparing for an administrative hearing. The Government investigators had made an inspection of a food processing plant and the plant in turn was suing the Government. When it came time to prepare the Government's case, we asked the investigators for their reports. They had none. We asked the investigators for their diaries. They had none. So, you can imagine what happened when these investigators took the stand to testify about what they had done approximately 2 years previously.

It can happen. You also must remember as investigators that there is always the possibility that your report will be turned over to the defense attorneys at the end of the trial and they can have a field day on those.

Some things like, "The firm's president is obviously violating the law and should go to jail," do not belong in a report. These things happen, and I have seen it. I have seen the defense attorneys massacre investigators on the stand who have such conclusionary information in their reports.

Conclusionary information does not belong in the body of a report. You may want to have a separate section headed, "Conclusions," but not in the body of the report.

The investigator is basically a collector of facts, and the judge as to whether or not we have a violation of the law rests with another level. It should not rest with the investigator who made the investigation.

Many times, the investigator may be required to copy documents. There is a possibility, and this happens very often, that months or years later he may be called upon to identify the originals of those documents that he copied. Unless the investigator has an excellent memory, there is no way that he can identify these documents unless at the time of copying, he placed his initial and the date on it in an inconspicuous location on the document, preferably the reverse side.

Many investigators get in the habit of placing their initials, the date, and then enclosing this information in a distinctive design; for example, a triangle or a square or a circle. In this way, they can identify what they did months or years later, because they are consistent in what they do.

This brings up another point. As an investigator, you should try to be consistent. If you get in the habit of doing things, you are going to always identify your mark at a later date if the need arises. Likewise, many times in an investigation an investigator may have to collect a sample of a defective device or some other article. Then, too, it may become necessary for the Government at a later date to verify the integrity of the sample from the time of collection to the point where it was received by the technician.

How can the Government do it? There are two ways. One; to maintain this integrity, the investigator must keep that device or that sample in his constant custody, in his possession, from the time of collection to the time he delivers it to the technician, or the analyst in the laboratory. Two; the other procedure, which the FDA usually uses, is to have the investigator wrap his sample or device thoroughly, seal it, and then put an official Government seal on those locations where the package can be opened; then he signs and identifies or dates the seal. Then it is the responsibility of the analyst to examine the seal and the condition of the package on receipt and note the results of his examination on his worksheet. For example, if the seal is broken, he should make that notation on his worksheet, because the sample's integrity has suspicion now.

This brings up another interesting point with laboratory records. We have the same problem in the FDA, and I am sure that you folks have the same problem. Many analysts feel that there is no reason for them to be careful because they will never testify. We found erasure marks for which we had no explanation on analysts' worksheets; we found deletions; we had cases where the analyst did not sign his worksheet. Years later or months later, we could not ask if he actually did the work. We have had another problem where a group of technicians or analysts analyzed the sample and when we get ready for trial, we cannot identify which analyst worked on which portion of the examination.

Some time ago, Tom Brown was preparing for an administrative hearing on some GE microwave ovens and he had an occasion to review the analytical worksheets, the technician worksheets. He indicated there were erasure marks, there were deletions. He could not tell from the worksheets whether or not the analyst had calibrated his instruments used in the examination of the microwave ovens. His records should have a complete story. If he calibrated his instruments, he should mark those down on his worksheet. Any cross-outs should be explained. He should sign his worksheet. If anybody has a solution how to get the analyst to do this constantly, we would like to hear about it, because they are a hard breed of animal to convince.

The only solutiuon I have found is that when we do prepare for trial, they usually panic because they know the mistakes they have made, but their answer is, "It will never happen to me. I will never have to testify," so many of them are very careless.

Finally, I would like to talk about photographs. Photographs are a permanent graphic documentation of observed conditions. An investigator should be aware of their value. They serve many purposes. Firstly, there is nothing like a photograph to revive one's memory on the witness stand. If you are on the stand, if you are having problems, trouble remembering the nature of your investigation, it is permissible for you to look at the photographs. Secondly, a series of photographs will help your supervisor in evaluating the case, as well as the government attorneys in preparing for their case.

Thirdly, there is nothing like photographs to present to a jury and to a judge to demonstrate the fact you are trying to make.

One disadvantage with photographs is that very often photographs do not tell the story by themselves. A photograph should be a complete story. If you show someone the photograph and if he has to ask what it is, it is no good. For example, during our work of inspections, say in a food plant, we may take a photograph of an insect; if it is taken from a long distance, if it looks like a speck of dust, it is not worth anything. It has to be a closeup. It has to be distinguishable as an insect to be of any value.

Subjects that can be photographed are plant layouts, equipment, manufacturing processes, records, labels, displays, environmental conditions, company bulletin boards, and so forth.

There are certain problems with photographs; the basic problem is that many investigators do not know how to use a camera. I think it is imperative for an investigator to be very confident and competent with a camera.

We can introduce photographs into evidence in a court of law by laying a foundation that basically indicates that the photograph is a correct representation of the conditions existing during the investigation period.

We are having a problem lately with management allowing the taking of photographs. Under no circumstances should an investigator ever ask management (unless your law specifically requires it) for permission to take photographs. You should act in a very professional manner; take your photographs as if you have a right to do so. If you asked permission, you may get some questions that you may not be able to answer, and it may allow management to have second thoughts about your taking those photographs.

Likewise, under no circumstances should an investigator ever pose a person or a thing unless this is explained in his report. We have seen it in FDA, an investigator may observe an employee sticking his hand in a vat of food, which is a no no, of course. But then, what he will do to get his picture, is to ask the employee to do that. This, too, is not recommended. It causes a problem, because that investigator under cross-examination can find himself in the box.

We also recommend that when you receive your prints back from the developer that you identify the photograph on the margin with your initial or your signature, the date the photograph was taken, and any sample number or exhibit number that you give to your photographs.

What I have attempted to do is to give you some information as to how the Food and Drug Administration handles their physical evidence. Again, I urge you to go back home to review what you are doing, and if you find a need for improvement or for doing something a little differently, do it.

LEGAL ASPECTS OF A REGULATORY INSPECTION AND ENFORCEMENT PROGRAM

Allen D. Johnson
Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission

I am pleased to be here in Seattle today and have the opportunity to attend and participate in your conference. When I was first asked to speak to you on the Legal Aspects of a Regulatory Program, I said, "Sure, be glad to." I thought at the time I could easily cover the subject in detail in a short period of time without much effort. But, as I began to prepare this talk and stay within my time allotment, I discovered that I must appropriately limit myself to a very broad and selected discussion of the source of regulatory power, some limitations, and how the inspection and enforcement program of the Nuclear Regulatory Commission operates.

The elements and legal aspects of any type of regulatory inspection and enforcement program, whether local, State, or Federal, depend on the activity to be controlled, the needs of the community and the authority establishing the program.

As you are all aware, in our land the repository of power remains with the people. The people first gave the several States certain powers as expressed in the respective charters and constitutions. Then, when the States formed the Union they transferred certain of those powers to the Federal Government as embodied in the U.S. Constitution. I mention this as a reminder that all governmental action must fall within the power granted by the people. Let me emphasize that what the people grant they may also take away.

First, we should understand that all Federal agencies are created by Congress and they may exercise only such powers granted to them as expressed in the statute which created and directs the agency. Obviously, from what was stated earlier, Congress may only delegate power which has been granted to it via the U.S. Constitution.

The Supreme Court has assumed the power to judge Federal action and determine whether those actions are within the powers granted to the Federal Government. In reaching such a decision, the Court not only looks at the powers as they are expressly stated but also holds that certain powers are implied which by necessity must exist to enable proper exercise of the expressed power. For example, Congress has the power to coin money. Since it seems obvious that it was never intended by the drafters of our Constitution that the Congressmen themselves would print and circulate the money, it follows by implication that Congress has the power to delegate to the Treasury Department the responsibility to carry out the actual performance of the granted power.

Another source of implied power of Congress flows from the "necessary and proper" clause of Article I. This clause states that Congress has the authority to make all laws necessary and proper to execute its expressed powers and all other powers vested in Government.

The significance of these Congressional powers becomes clear when one addresses the current situation in our country in which nonelected civil servants exercise broad authority over our lives. If it cannot be established that Congress originally has a particular power from the Constitution which it then properly delegated to an agency, then all the actions of all employees of that agency would be unconstitutional and abusive to the American people.

There has been voiced in our land among citizens, legislators, and courts a concern about what has been termed "the tyranny of bureaucracy." The Constitution not only grants powers to the Government, but it also specifically protects certain inalienable rights of citizens as set down in the Bill of Rights. Although these rights expressly limit the Federal Government's action, the Supreme Court has made most of the Bill of Rights applicable to restrain State action as well through the equal protection and due process clause of the 14th Amendment to the Constitution. These rights are deemed to have been retained by the people and are considered fundamental in a free society and beyond the powers of Government.

For example, one of these rights that is of prime importance and applicable to all regulatory agencies is the 4th Amendment to the U.d. Constitution. This amendment provides that the "right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation and particularly describing the place to be searched and the person or things to be seized." This right has been found by the U.S. Supreme Court to be a fundamental right of the people applicable to all governmental entities in the United States.

To assure that the people retain their freedoms, powers and rights and that Government serves its proper role to which it has been called, certain principles must be kept in front of us who serve in the role of regulators. For example, I like the following:

1. Our Government is called to serve, not to rule.
2. Power either corrupts and destroys or creates and gives life.
3. Liberty is too priceless to be surrendered to administrative zealots.

I would hasten to suggest that each regulatory office should have a short motto or principle of their own making to continually remind them of their role and purpose. It's so easy to forget!

Since I am most familiar with the NRC inspection and enforcement program, let me use that program to show how a Federal regulatory program is properly established and executed. The same would be applicable to any type of regulatory agency whether local or State.

One of the specific powers of Congress allowing passage of the Atomic Energy Act as amended is the power to control and regulate interstate commerce. This is declared in Chapter 1 of the Act where Congress has stated that source, byproduct and special nuclear material must be regulated in the national interest to provide for the common defense and security and to protect the health and safety of the public; and that possible interstate damage from operation of facilities places the operation of such facilities in interstate commerce.

Congress created the Atomic Energy Commission in 1946 to control research and development of atomic energy. The Act was subsequently amended in 1954 to broaden the function of the Commission from purely research and development to development and regulation of private use of atomic energy. Then in 1974, because in order to eliminate even a hint of a conflict of interest between the developmental and regulatory functions, Congress, through the Energy Reorganization Act, abolished the AEC and divided its former activities between the Energy Research and Development Administration and the Nuclear Regulatory Commission. The basic source of NRC's authority and directive still flows from the Atomic Energy Act since the Reorganization Act deals primarily with the division of activities between the two agencies. The Reorganization Act transferred all licensing and regulatory authority to NRC.

The Office of Inspection and Enforcement within NRC was created by the Commission through its general powers. The office is charged with the responsibility of performing inspections of persons holding an NRC license to verify that the regulated activities are being performed in accordance with the terms and conditions of the NRC license and the applicable rules and regulations of the Commission.

When a licensee's activities are found to be in violation of regulatory requirements, the Office of Inspection and Enforcement has been given the authority to initiate the necessary administrative action to assure that appropriate corrective measures are taken to achieve and maintain compliance with the requirements. Please note that NRC is limited to administrative action. Chapter 18, Section 221, of the Atomic Energy Act of 1954 restricts NRC enforcement activities to administrative actions. Only the Attorney General of the United States has the authority to bring a judicial action against any individual or person for a criminal violation of law or regulatory requirement.

Another important statute that bears on all Federal agencies, including NRC actions, is the Administrative Procedure Act. This statute establishes broad requirements for administrative agencies to follow. The Act not only establishes certain legal procedures governing licensing, ajudication and rulemaking, but also includes substantive safeguards for citizens subject to agency action. These include various due process procedures such as opportunity for hearing, cross-examination, and judicial review.

I like to view inspection and enforcement as inseparable activities; in fact, they really are one and the same. During the past 14 years, I have come to believe that the most effective enforcement action results quite naturally from the inspection of the regulated activity. Generally speaking, during an inspection, the individuals responsible for an activity will be the first to recognize their shortcomings or deficiencies and will voluntarily initiate appropriate corrective measures. I have found this to be generally true unless, and to me this is vital, the regulatory plays the game of "I got ya" in which case the "inspectee" will do almost anything except that which the inspector thinks is required. I am sure you will agree with me that such a reaction should be expected from how we, as regulators, personally respond under similar situations.

Most people, however, view the two functions as separate, therefore, let me now speak first to inspection.

NRC inspections meet the equal protection and due process requirements of fairness, evenhandedness, and uniformity in application and have thus avoided being attacked as discriminatory, arbitrary, or unfair. This has been accomplished through our use of written procedures that have been prepared and reviewed by experienced and qualified personnel and approved by established authority. These procedures provide the required directives to assure that trained and qualified inspectors carry out their prescribed duties within legal bounds to effectuate the declared purpose of the Congress as expressed in the Atomic Energy Act as amended.

As a caveat to any regulator, if your program fails to meet the equal protection and due process concepts just mentioned or your inspection procedures or rules are ambiguous and therefore subject to differing interpretations and application, your program and actions thereunder will be subject to attack and may well be voided by a court of law.

Generally, if your documents are written in clear ordinary language so that the ordinary people who speak the language can understand what was intended and your program is implemented in accordance with those intentions, your actions will in all probability be considered legal and upheld so long as they are reasonably related to the directives of the statute under which you operate.

Now let us take a look at enforcement.

The Atomic Energy Act of 1954 empowered the Commission to take administrative action and, if warranted, impose sanctions upon any person who violates regulatory requirements. Sanctions currently used by the Commission for the purpose of enforcing regulatory requirements consist of the following:

1. Notice of Violation.
2. Civil Penalties.
3. Order to Cease and Desist.
4. Order Modifying, Suspending, or Revoking a License.

These sanctions are imposed pursuant to due process of law by means of internal NRC procedures developed by our management and counsel.

The enforcement procedures establish three major severity levels commensurate with the significance of particular noncompliance of the several regulatory requirements. In decreasing order of severity there are:

1. Violations,
2. Infractions, and
3. Deficiencies.

Generally speaking, the failure to maintain a record is considered minor and would be classified as a deficiency; whereas, for example, failure to perform surveillance required by the license may have greater significance and would be considered an infraction. Violations are used for items of major significance. Items of noncompliance and their severity level are described in a formal inspection report to the licensee which becomes part of our records and is posted in various public document rooms and/or local libraries.

To guide us in the selection of the appropriate sanctions, our procedures establish a point system which is correlated to the severity of the noncompliance involved. Deficiencies are assigned 2 points, infractions 10 points, and violations 100 points. If during any one inspection, the point count for all items of noncompliance identified equals or exceeds 100 points we automatically evaluate the circumstances to determine whether civil penalties should be imposed. If a repeat item of noncompliance is identified, we double the point count for that item. Similarly, if a second repeat were to occur we would quadruple the point count for that item and continue to double the point count for each recurrence. This allows us the use of strong sanctions for repeated noncompliance. It should be kept in mind, however, that the 100 point value is only a trigger level to assure that an evaluation is made.

Once an inspector and his regional management have decided to recommend a civil penalty the action is subject to a multiplicity of reviews before the Notice of Proposed Civil Penalty is signed and issued. This is done to assure that all pertinent information has been considered, that our procedures are being properly executed, and ultimately that our action will be sustained if we should be challenged in court.

Other sanctions available (Order to Cease and Desist or Orders Modifying, Revoking, or Suspending a License) are used less frequently. Our procedures, however, provide the guidance for imposing these sanctions as well as the prerequisities to be met.

To conclude, let me say that all regulatory bodies in the United States must meet the following requirements.

1. They must have the power that they intend to exercise.

2. They must exercise the power granted in accordance with the provisions of the equal protection and due process requirements of the 14th Amendment to the U. S. Constitution, which in essence is to be fair and uniform.

3. They must understand that people in our great land are presumed to follow the law until proven otherwise.

PREPARING TO ACT AS A WITNESS

Richard A. Lane
Bureau of Occupational and Institutional Hygiene
Department of Environmental Services
District of Columbia

Historically, with possibly one exception, New York City, the radiological health programs through the United States have pursued a nonlegalist approach in obtaining compliance of x-ray standards.

With the advent of the Radiation Control for Health and Safety Act of 1968 and the subsequent development of performance standards for x-ray equipment by the U.S. Food and Drug Administration's Bureau of Radiological Health, we have seen little or no legal action taken by the Bureau to obtain compliance to these standards. To date, the Federal Bureau of Radiological Health has been able to achieve desired compliance of approximately 180 cases by friendly persuasion. In addition to the friendly persuasion method, the Bureau has obtained one injunction, and one civil penalty has been levied against an assembler with the potential of one additional civil penalty. This action has taken place in only 2 of 10 regions.

In discussions with members of the Bureau staff, it was learned that only approximately 10 percent of new certified medical x-ray units are being evaluated. It has also been indicated that additional monies are needed to provide increased coverage by more States and/or increase the percentage of units surveyed by any one of the particular States presently involved in the Compliance II survey program.

Mr. Robert Britain in his presentation last year before this Conference stated that approximately 30 percent of all units surveyed under the Compliance II program have been found to be in noncompliance. It is interesting to note that this 30 percent has remained fairly constant through the past 3 years. Dr. Howard McMartin of NIOSH, a number of years ago, prior to the passage of 90-602, stated that we needed such a law to prevent the constant flow of antiquated equipment into the public health vast kettle or jug. The law, P.L. 90-602, has not accomplished that end, at least not to date. With only a survey and at least a 30-percent noncompliance, there is a definite need for increased surveillance and increased legal action.

As I proceed with this paper, please keep this in mind, that I am not an attorney, and that the legal axiom that a man who acts as his own attorney has a fool for a client is somewhat appreciable.

I will not be attempting to cover the areas of relationships between program managers and attorneys, but simply what is needed when you go to court.

There are 3 basic elements of concern when you are preparing to go to court; these are (1) evidence development, (2) court presentation, and (3) courtroom deportment.

In gathering evidence, the inspector must be able to recognize, collect, and effectively present admissible evidence that a violation is occurring or has occurred.

There are two types of evidence; direct and circumstancial. Direct evidence is information that directly and instantaneously brings about a conclusion upon the disputed issue. Circumstantial evidence is information that does not relate directly to the issue of fact, but relates directly to another fact, which once established relates to the question in issue.

Documents, photographs, previous survey forms, and letters are forms of evidence. Caution should be used when photographs are going to used as evidence. You should be skilled in photography and know how to properly plan a series of pictures that tell the story without the need to explain in detail.

An important part of evidence gathering is to do a complete evaluation. I recently reviewed a survey conducted by an individual from one of our great States. The information was provided to prove the conditions associated with a certain institution. The inspector reported that the weather was hot and humid. He failed to indicate in the report the particular day or time of his conclusion, he also concluded this without the aid of a thermometer or psychrometer. He also indicated that lead shielding should be provided in the x-ray room. This was accomplished by his senses since he did not have instrumentation to measure radiation. He indicated that fumes were a problem in the paint shop, again without proper calibrated instrumentation.

The first and most important limitation that the inspector should appreciate is, when he testifies about an inspection he is practically always called as a fact witness and not as an expert witness. His testimony may be used to supply the facts on which a later expert witness will base conclusions.

The value of testimony depends, first, upon the witness's capacity to have observed the facts; second, upon his ability to remember what he has seen and not to confuse knowledge with belief and, last, upon his power to express what he has, in fact, seen or remembers. The inspector must be able to recall masses of data that has been collected weeks or months earlier. An inspector will have great difficulty if he must rely on a poorer than average memory.

Generally, the inspector is required to testify from memory; however, under certain situations, notes and memorandums may be used. The inspector attorney will be in the position to advise in these cases. Remember, if you do not recall or do not know the answer to the question do not hesitate to say so.

The experience gained by the District has been through the route of expert witness. Remembering the main difference between an expert and a fact witness is that both must know the facts with the expert testifying to conclusions. In preparing to act either as an expert or fact witness, the basic preparation is the same.

I will attempt to highlight a few areas that should or must be considered by the individual preparing to serve in either capacity.

1. Reviewall pertinent documents relating to the issue, this includes past and current. Knowing the subject matter is of vital importance.

2. Know the standards which you used in your evaluation. This includes the public health reason for the particular standard. If the collimation is not properly calibrated or the timer is not reproducible, what is the public health consequence?

3. If depositions are taken from other experts or witnesses involved, make sure you review and understand clearly what they are saying.

4. The majority of the time you as an expert or representative will have to educate the attorney who is representing you.

5. You will find yourself in the position of educating the court (judge) in the technical issues; especially in terminology that they can understand while retaining your technical sophistication.

6. Remember you are the expert in your field and you know more than the defense attorney cross-examining you.

7. In reviewing the issues always be prepared to answer the most logical questions that

may be asked as well as the illogical questions.

8. If you do not understand the question say so.

9. Never offer conclusions under cross-examination.

10. Be prepared to answer questions the judge may ask.

11. Know the judge - liberal, conservative, hard of hearing, which ear; do technical areas need to be explained in simple detail?

12. Even if the defense attorney is asking the questions, speak to the judge. Be clear and distinct. Do not be afraid of the judge or defense attorney. Pamper them.

13. Do not be nervous, the defense attorney will pick it up.

14. When sitting in the courtroom, make yourself as inconspicuous as possible.

15. Do not lose your patience or temper while testifying.

16. Take your time in answering questions, do not be an eager beaver.

17. Do not compare one situation against another. Each case is separate and distinct.

There are many other factors that must be considered such as mode of dress, posture, appearance, and so forth; however, the most important in my opinion is coming into the courtroom prepared. Know your facts, all pertinent dates and times should be checked. Arrange all documents and tidbits in order so that the testimony will be presented without fumbling.

Many of the most important achievements of public health have had the support of laws and ordinances requiring conformity to specified standards. However, please do not reach the conclusion from my presentation that the enforcement of established standards is the only or best way to achieve compliance.

A program administrator has three main tools or methods of approach at his disposal--education, persuasion, and enforcement and the extent to which he successfully blends and balances these tools is one of the best measures of true administrative ability. The enforcement power must be considered a powerful factor in the development of effective public health, but it has definite limitations.

Based on the experience of the past 3 years of Compliance II survey reports, and if we are to improve the conditions of the new x-ray units in the field, and despite all wishes to the contrary, every active radiological health program director will sooner or later find himself in court. If this thought comes to fruition I hope this presentation has been of some help.

USE OF OBSTETRIC ULTRASOUND IN U.S. HOSPITALS, 1974

Paul L. Roney
and
Peggy Hamilton
Bureau of Radiological Health, FDA

The Division of Biological Effects of the Bureau of Radiological Health, conducted a study on the use of ultrasound for the diagnosis of obstetric conditions in the United States during 1974. The study consisted of sending questionnaires to a sample of 1,000 short-term general and maternity hospitals in the United States. The sample was a stratified random sample; that is, the hospitals were stratified by the annual number of births with a progressively greater proportion of hospitals with large newborn services than hospitals with smaller services. For example, all hospitals that recorded an annual number of births over 2,500 were contacted, but only 2.7 percent of hospitals that recorded less than 200 births per year were contacted.

The response rate for the survey was 96 percent. One major factor for the high response rate was that the questionnaire was easy to complete for over 600 hospitals that did not use diagnostic ultrasound for obstetric conditions. The study indicates that approximately 4 percent of hospitals recording less than 400 births per year used diagnostic ultrasound in obstetrics and the percentage increased steadily by size of obstetric service until approximately 54 percent of hospitals recording more than 2,000 births per year stated that they used ultrasound for diagnosis of obstetric conditions. In all, it is estimated that approximately 16 percent of the obstetric services in the United States used diagnostic ultrasound and that about one-third of the births in the United States during 1974 were delivered in these hospitals. A small survey of hospitals conducted in 1971 indicated that 13 percent of the hospitals had diagnostic ultrasound equipment but that was the only question asked, no questions were asked on how the diagnostic ultrasound equipment was used.

Of the hospitals that reported they used diagnostic ultrasound for obstetric conditions in 1974, a number of indications for use of obstetric ultrasound were reported. Seventy-two percent of the hospitals reported they used diagnostic ultrasound for fetal cephalometry, 88 percent for placental localization and 59 percent for fetal monitoring during labor. Other frequently reported indications for use were suspected molar pregnancy, fetal heart detection in early pregnancy, suspected multiple pregnancy, and fetal well being.

The estimated number of women exposed to ultrasound for the diagnosis of obstetric conditions in 1974 was 470,000. Approximately 35-40 percent were examined more than once. Those 470,000 women represented approximately 15 percent of the recorded live births in the United States in 1974.

The hospitals estimated that almost 55 percent of the obstetric ultrasound examinations performed in 1974 used the Poppler technique, about 30 percent used the pulse echo technique, and about 15 percent used both techniques.

The use of obstetric ultrasound by trimester of pregnancy varied widely from hospital to hospital. Of the hospitals reporting in the survey, 20 percent reported they did not use obstetric ultrasound during the first trimester; the vast majority of the remaining hospitals reported that less than 20 percent of their obstetric ultrasound examinations were performed on women during their first trimester. Approximately half of the hospitals reporting in the survey stated that more than 70 percent of all obstetric ultrasound examinations were performed on women during their third trimester.

Generally speaking, the directorship of the use of obstetric ultrasound was divided about equally between the OB department and the radiology department.

For the hospitals reporting, around 50 percent stated that there were 3 or fewer operators of the equipment. Also, we received reports such as "All the nurses on the ward."

In regard to the question of where the hospitals are located that use obstetric ultrasound, about 80 percent are in SMSA's of 250,000 population or more. Only 12 percent were recorded as being in rural areas.

The data presented here are on the use of obstetric ultrasound in short-term general and maternity hospitals only. These data do not include any examinations performed outside hospitals such as in private offices and clinics.

OVERVIEW OF NONIONIZING RADIATION PROGRAMS OF NIOSH

G. E. Moss
National Institute of Occupational Safety and Health

This presentation will attempt to answer questions generally asked concerning the National Institute for Occupational Safety and Health (NIOSH) and its role in the field of nonionizing radiation. First, what is NIOSH? Second, how does NIOSH define radiation? Third, what are the potential occupational radiation hazards? Fourth, what is the population at risk? Fifth, what has NIOSH accomplished in the radiation area? Finally, what are the future NIOSH goals in the radiation area? Answers to these questions should give a good overview on the depth and character of the NIOSH radiation program.

NIOSH is a major component of the Center for Disease Control (CDC) in the Department of Health, Education, and Welfare (HEW). NIOSH headquarters is located in Rockville, Maryland, with laboratory facilities in Morgantown, West Virginia, and Cincinnati, Ohio. NIOSH has approximately 900 employees with about 60 percent located in Cincinnati. Figure 1 is a very simplified organizational chart. It depicts the Bureau of Radiological Health (BRH) and NIOSH within HEW and the Occupational Safety and Health Administration (OSHA) within the Department of Labor. There are, of course, many other organizational components than those depicted.

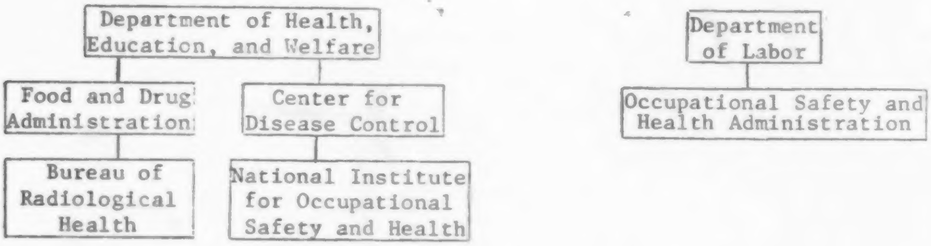

Department of Health, Education, and Welfare
Food and Drug Administration
Center for Disease Control
Bureau of Radiological Health
National Institute for Occupational Safety and Health
Department of Labor
Occupational Safety and Health Administration

Figure 1. Simplified orgainizational structure.

One of several important missions for NIOSH under Public Law 91-596 is to produce criteria documents, which are then forwarded to OSHA for its consideration in promulgating standards. Another important mission is to conduct upon request hazard evaluations of chemical and physical agents found in the workplace.

Within NIOSH radiation is considered as a physical agent. The term physical agent can be defined as an entity without substance (i.e., possessing minimal matter), yet capable of affecting the biological mechanisms of an exposed worker. At NIOSH, the physical agents are classified into three general components: Oscillatory vibrations, atmospheric variations, and radiation. Radiation studies encompass the ionizing, ultraviolet, visible, infrared, microwave, and radiofrequency portions of the electromagnetic spectrum.

The radiation work at NIOSH incorporates input from four major research programs as shown in figure 2. For example, as a result of information obtained from a hazard evaluation, sufficient concern may be generated to initiate additional biological studies to define the degree of risk. After these studies have been performed, the results may be used to devise control measures or develop unique protective devices to minimize or eliminate the risk. No single research input is more important than any other and all inputs are necessary to properly address the hazard.

- Biological Effects Studies
- Protective Devices
- Control Measures
- Hazard Evaluations

Figure 2. Areas of NIOSH radiation research.

The Physical Agents Effects Branch (PAEB) does much of the radiation work related to biological hazards at NIOSH. The branch has 19 people who work in two sections: Radiation and Noise. The Radiation Section has a staff of five professionals and the workload is divided into three general areas: ionizing, optical, and microwave/radiofrequency. Table 1 lists most of the known human biological effects that have been observed in these areas. Additional information about the nature of biological effects encountered in the workplace can be found in the NIOSH publication entitled "Occupational Diseases - A Guide to their Recognition" (1).

In a recent study, PAEB estimated the number of workers who are potentially exposed to electromagnetic radiation by sex and occupational job category (2). The data were based on available Bureau of Census population figures, NIOSH reports and studies, and other Government reports. The population potentially exposed by 1980 to optical, microwave/radiofrequency, and ionizing radiation was estimated to be 111, 21, and 7 million workers, respectively. In many cases, workers may be exposed to more than one type of radiation, and, as expected, certain occupations experience a greater degree of risk than others.

What has NIOSH accomplished in the radiation field? A brief description of the studies completed will be given for each of the three work areas, starting first with the ionizing area.

NIOSH was asked by the Air Transport Association in 1975 to investigate and document whole-body and extremity radiation doses received by airport personnel performing security searches. The published findings indicate that no measured dose equivalent exceeded the OSHA limits. Moreover, the low personnel exposures documented in this study support the effectiveness of the existing FDA cabinet x-ray standard (3). NIOSH investigated in 1976 potential problem areas in the industrial use of ionizing sources not regulated by the Nuclear Regulatory Commission. Records from eight State radiation control programs were examined to determine various statistics useful in identifying hazardous conditions. This report (4) should be of interest to all State Radiation Control Directors. In another radiation-related matter, NIOSH was recently asked to document radiation levels from video display terminals in newspaper offices. The findings of this report will soon be available as a NIOSH report (5).

Table 1. Known human biological effects from electromagnetic radiation exposure.

Microwave & radio-frequency radiation	Optical radiation	ionizing radiation
Death	Skin cancer	Death
Genetic Effects	Squamous cell epithelioma	Cancer
Teratogenic effects	Basal cell epithelioma	Leukemia
Behavioral effects	Herpes Simplex lesions	Sterility
Cataract	Cataract	Cataract
Acoustic response	Retinal damage	Radiodermatitis
Nervous system disorders	Genetic alteration	Ulcerations
Headache	Erythema	Erythema (burns)
Blood level changes	Keratoconjunctivitis	Genetic alteration
Loss of memory	Heat stress	Blood cell changes
Dullness	Cutaneous burns	Malaise
Sleepiness	Variance in biological rhythms	Fever
Sinus arrthymias	Asthenopia	Nausea
Arrhythmia		Weakness
		Shock
		Diarrhea
		Life span shortening
		Anorexia

NIOSH has recently completed a literature review on radiation carcinogenesis. This review was performed by the Franklin Institute Research Laboratories and summarizes the world literature published since 1973 pertaining to both ionizing and nonionizing radiation induced cancer. Points emphasized in the project included: radiation types documented to be human or animal carcinogens; types which may act as promoters; dose response relationship and wavelength (energy) dependence; and recommendations for further study. A three-volume report is currently in press (6-8). This report should be of interest to State programs since it will help in defining nonionizing radiation priorities. In addition, there have been requests for other studies, most notable, one on a coal thickness gauge device which uses radioactive material. We have also closely worked with other NIOSH components and the Department of Defense on personnel working with radar units. While it is apparent that PAEB has been involved with ionizing radiation, our major programmatic interest is in nonionizing radiation.

PAEB has done considerable work in the ultraviolet, visible, and infrared radiation regions of the electromagnetic spectrum (denoted optical radiation). The major emphasis in the optical region has been on ultraviolet (UV) with the completion of a criteria document, development of hazard monitors, calibration techniques, and continued biological effect research. All reports of the UV work have been published and are available from NIOSH (9-13).

Figure 3 shows one of the two NIOSH UV hazard monitors. This monitor is portable, lightweight, and designed to be used according to methodology noted in the NIOSH UV Criteria Document. At present, there is only one commercially available instrument designed to measure UV according to the NIOSH recommended standard. Within the next few months a comparison between the two NIOSH meters and the commercial meter will be completed and the results published by NIOSH.

Another major research effort involved evaluation of optical radiation produced by various welding processes. This effort is being performed with both inhouse and contract support and includes a cooperative effort with the American Welding Society involving field measurements of welding arc spectra. At the present time data are available on over 300 different welding events. Inhouse work involves epidemiology studies, in conjunction with the Bureau of Labor

Statistics, determining transmission levels through transparent welding curtains, and an evaluation of the welding factors affecting optical radiation levels.

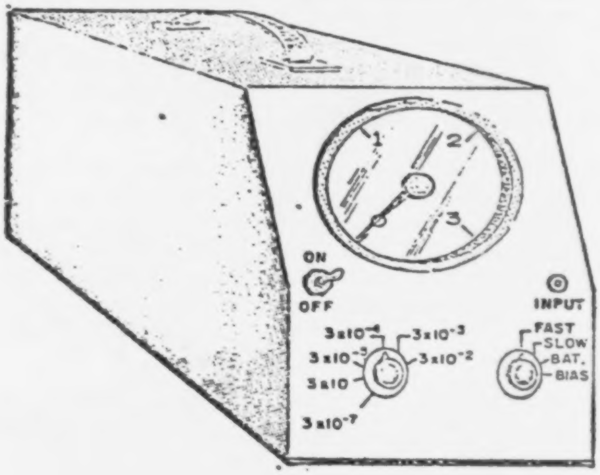


Figure 3. The ultraviolet hazard monitor.

Infrared radiation (IR) has been implicated as a cataractogenic agent. However, detailed exposure studies are few in number and vary in interpretation. PAEB has just awarded a contract to obtain threshold data for cataractogenesis in the near-IR region. PAEB is also in the process of completing a literature review on biological effects encountered by workers exposed to broadband noncoherent infrared sources. In conjunction with this review, PAEB was asked by the World Health Organization to prepare a manual on IR hazards and control procedures. Pending results of the IR cataract study, consideration is being given to the development of an IR hazard monitor.

In other optical radiation areas, NIOSH in 1974 sponsored a symposium on low-level illumination (14), produced a laser hazard classification guide in 1976 (15), measured several video display terminals, and is completing some preliminary light emitting diode (LED) measurements.

PAEB has also devoted considerable effort to the microwave/radiofrequency radiation. Major accomplishments include the fabrication of an exposure chamber (16,17), development of near-field electric and magnetic field meters (18,19), and conducting field surveys. Almost all of the equipment and instrumentation developed have been built with the help of the National Bureau of Standards.

Over 1,400 measurements on various RF sources typically found in the workplace have been completed (20). At least 75 percent of the sources surveyed exceeded the current personnel radiation protection guides set by ANSI.

Many of these sources were operated by women of childbearing age. In view of this finding, plus evidence that teratogenic effects have been induced in humans and animals exposed to RF radiation, NIOSH has recently initiated a program to investigate the teratogenic effects. This study is being conducted on rats at frequencies under 40 MHz where most industrial RF sources operate. The results will be used to define better personnel exposure standards.

Because of the difficulties in making meaningful biological measurements in the area from 10 to 300 MHz, it has been necessary for PAEB to acquire information on special techniques such as phantom modeling, six-port analysis, and dielectric measurements. Since animals are used, it is necessary to extrapolate the animal absorbed doses to a predicted human insult. Modeling techniques have been shown to be valid for this purpose (21). Before models can be used, however, it is necessary to study the electrical characteristics and properties of various materials to determine reasonable conformity with the electrical properties of the body (22). Since absorbed dose values rather than change in temperature are of more importance in RF biological measurements, PAEB has worked with NBS on the development of new measurement systems. Such a system is undergoing testing at this time.

Our last question is "What will NIOSH be doing in the future with the radiation area?" Most of our future work will probably involve the optical and microwave/radiofrequency radiation work areas. In the optical area, we will be developing criteria document input for infrared radiation, visible radiation, welding/brazing, and roofing industries. Moreover, our laboratory facility is designed to carry out synergistic studies involving chemical and physical agents. This is extremely important because of the large number of chemicals in the workplace. Very little data exist on the synergistic relationship between optical radiation and the more than 15,000 chemicals used in the workplace.

A criteria document in the microwave/RF area is scheduled for completion within 2 years. The possibility of doing synergistic studies with RF is also quite appropriate.

In conclusion, PAEB is definitely involved with radiation protection concerns in the work environment. This overview has presented some aspects of our programmatic aims and directions with the intent to give you a better understanding of our efforts in meeting today's challenges in occupational radiation protection.

DISCUSSION

FROM THE FLOOR: Could you comment very briefly about NIOSH's work in ultrasound?

MR. MOSS: I believe it would be fair to say that our work in this area is very limited. A project proposal by PAEB on industrial ultrasound could not be undertaken last year because of other priorities in the Noise Section.

FROM THE FLOOR: In your slide, you indicated the effects of microwaves, but do you have documents indicating numbers of people who have shown these effects?

MR. MOSS: No, not numbers of people showing each effect. However, we have references for the effects shown on the slide.

FROM THE FLOOR: Are these available?

MR. MOSS: Yes.

FROM THE FLOOR: Do you have a bibliography?

MR. MOSS: In the text "Occupational Diseases - A Guide to their Recognition," there is a large bibliography on microwave/radiofrequency effects.

REFERENCES

1. Occupational Diseases - A Guide to their Recognition, revised edition. DHEW (NIOSH) Publication No. 77-181. (June 1977).

2. Moss, C.E., D.L. Conover, W.E. Murray, and A. Kohre. Estimated Number of United States Workers Potentially Exposed to Electromagnetic Radiation. Paper presented to American Industrial Hygiene Conference, New Orleans, Louisiana, May 26, 1977.

3. Sensintaffar, E.L., C.E. Moss, and W.H. Parr. Documented Personel Exposures from Airport Baggage Inspection Systems. DHEW Publication No. (NIOSH) 77-105 (1976).

4. Cohen, S.C., S. Kinsman, and H.D. Maccabee. Evaluation of Occupational Hazards from Industrial Radiation: A Survey of Selected States, NIOSH contract 210-75-0071. DHEW Publication No. (NIOSH) 77-142 (1976).

5. Moss, C.E., W.E. Murray, W.H. Parr, J. Messite, and G.J. Karches. An Electromagnetic Radiation Survey of Selected Video Display Terminals. In Press. (1977).

6. Cunningham-Dunlop, S., B.H. Kleinstein, and F. Urbach. A Current Literature Report on the Carcinogenic Properties of Ionizing and Nonionizing Radiation -- Part I: Optical Radiation. NIOSH contract 210-76-0145. In Press. (1977).

7. Dwyer, M.J. and D.B. Leeper. A Current Literature Report on the Carinogenic Properties lof Ionizing and Nonionizing Radiation -- Part II: Microwave and Radiofrequency Radiation. NIOSH contract 210-76-0145. In Press. (1977).

8. Dwyer, M.J. and D.B. Leeper. A Current Literature Report on the Carcinogenic Properties of Ionizing and Nonionizing Radiation -- Part III: Ionizing Radiation. NIOSH contract 210-76-0145. In Press. (1977).

9. Criteria for a Recommended Standard. . .Occupational Exposure to Ultraviolet Radiation. DHEW Publication HSM 73-11009 (1972).

10. Madden, R.P. Ultraviolet Transfer Standard Detectors and Evaluation and Calibration of NIOSH UV Hazard Monitor. Interagency Agreement NIOSH-IA-73-20. DHEW Publication No. (NIOSH) 75-131. (1975).

11. Ultraviolet Hazard Monitor - Prototype Description. Final Report for NIOSH contract HSM-99-72-144. (1973).

12. Pitts, D.G. and A.P. Cullen. Ocular Ultraviolet Effects from 295 nm to 335 nm in the Rabbit Eye. NIOSH contract No. CDC-99-74-12. DHEW (NIOSH) Publication No. (NIOSH) 77-130. (1976).

13. Pitts, D.G., A.P. Cullen, and P.D. Hacker. Ocular Ultraviolet Effects from 295 nm to 400 nm in the Rabbit Eye. NIOSH contract No. CDC 99-74-12. DHEW Publication No. (NIOSH) 77-175. (1977).

14. Heins, Allan P. (Symposium Chairman). The Occupational Safety and Health Effects Associated with Reduced Levels of Illumination: Proceedings of Symposium. DHEW Publication No. (NIOSH) 75-142. (1974).

15. Sliney, D.H. et al. Laser Hazard Classification Guide. Interagency Agreement NIOSH IA-76-26. DHEW Publication No. (NIOSH) 76-183. (1967).

16. Greene, F.M. Development of an RF Near-Field Exposure Synthesizer (10 to 40 MHz). Interagency Agreement NIOSH-IA-75-16. DHEW Publication No. (NIOSH) 76-160. (1976).

17. Greene, F.M. Measurement of RF Power-Absorption in Biological Specimens. Interagency Agreement NIOSH-IA-75-16. DHEW Publication No. (NIOSH) 77-146. (1977).

18. Greene, F.M. Development of Magnetic Near-Field Probes. Interagency Agreement NIOSH-IA-74-12. DHEW Publication No. (NIOSH) 75-127. (1975).

19. Belsher, D.R. Development of Near-Field Electric Energy Density Meter Model EDM-2. Interagency Agreement NIOSH-IA-75-13. DHEW Publication No. (NIOSH) 75-140. (1975).

20. Conover, D.L. RF (10-40 MHz). Personnel Exposure-Industrial Hygiene Problems. Paper presented to American Industrial Hygiene Conference, New Orleans, Louisiana, May 26, 1977.

21. Guy, A.W., M.D. Webb, and J.A. McDougall. RF Radiation Absorption Patterns: Human and Animal Modeling Data. Interagency Agreement NIOSH-IA-75-30. DHEW Publication No. (NIOSH) 77-183. (1977).

22. Toler, J. and J. Seals. RF Dielectric Properties Measurement System: Human and Animal Data. NIOSH contract No. 210-76-0136. DHEW Publication No. (NIOSH) 77-176. (1977).

PROBLEMS AT INACTIVE OR ABANDONED FUEL CYCLE FACILITY SITES

W. T. Crow
Nuclear Regulatory Commission

The purpose of this paper is: (1) To discuss the past problems at fuel cycle sites and the current efforts to deal with these problems; (2) to discuss NRC's approach, which is to obtain decommissioning plans and financial surety arrangements to carry out these plans at the time of licensing; and (3) to emphasize the need to learn from these past mistakes to assure that similar problems will not be created in the future. For simplicity, I will break the discussion into two categories; uranium mills and other fuel cycle sites.

URANIUM MILLS

In response to a Congressional mandate in 1974, ERDA, EPA, and the States involved embarked upon a joint evaluation of problems associated with inactive mill tailings sites. A total of 22 inactive mill sites were identified, which contained an estimated 25 million tons of tailings. The evaluation was divided into two phases. The first phase, which is completed, was a preliminary evaluation to determine site conditions and served as the basis for a detailed engineering assessment where necessary. The second phase includes an evaluation of the problems, an examination of alternative solutions, and the preparation of plans for and cost estimates of remedial actions.

ERDA was designated by Congress as the lead agency with respect to the assessment of the health impact of mill tailings at inactive sites and for developing plans and recommendations for remedial actions for these sites, where appropriate. The Phase II studies are nearing completion, and reports for all of the sites should be available from ERDA within the next several months. When these studies are completed, ERDA may propose legislation to Congress for any necessary remedial actions. The Nuclear Regulatory Commission staff is working closely with ERDA to define what NRC's involvement should be in these remedial action programs. At the present time, NCR's participation involves: (a) working with ERDA and EPA in developing standards and criteria for mill tailings disposal sites and (b) review and comment on ERDA recommendations for remedial actions.

NRC is in the process of establishing a regulatory program to avoid, in the future, the problems now being experienced at inactive mill sites. Uranium mills are licensed by the Commission under Title 10 Part 40 of the Code of Federal Regulations. The licensing process for uranium mills involves a safety and an environmental review, which includes considerations relative to mill tailings.

The NRC staff is now in the process of preparing a generic environmental impact statement on uranium milling. The purpose of this statement will be to assess the environmental impact of uranium milling operations, including management of uranium mill tailings, and to provide an opportunity for public participation in decisions concerning any proposed changes in NRC regulations or regulatory authority based on this assessment. It is the intention that rules for regulation of uranium mill tailings will be developed out of information derived from the preparation of the generic statement and the conclusions resulting from the assessment of alternative procedures for mill tailings waste management.

During the interim period, while the generic environmental impact statement is being prepared and associated regulations developed, the staff has instituted a practice that requires establishment of an acceptable tailings management program prior to issuance or renewal of a license. Both of these types of actions will be accompanied by individual environmental impact statements containing specific plans for tailings management programs that will become conditions of the license.

The performance objectives established by the staff for an acceptale mill tailings waste management program are as follows:

Siting and Design

1. Locate the tailings isolation area remote frompeople such that population exposures would be reduced to the maximum extent reasonably achievable.

2. Locate the tailings isolation area such that disruption and dispersion by natural forces is eliminated or reduced to the maximum extent reasonably achievable.

3. Design the isolation area such that seepage of toxic materials into the groundwater system would be eliminated or reduced to the maximum extent reasonably achievable.

During Operation

4. Eliminate the blowing of tailings to unrestricted areas during normal operating conditions.

Post Reclamation

5. Reduce direct gamma radiation from the impoundment area to essentially background.

6. Reduce the radon emanation rate from the impoundment area to about twice the emanation rate in the surrounding environs.

7. Eliminate the need for an ongoing monitoring and maintenance program following successful reclamation.

8. Provide surety arrangements to assure that sufficient funds are available to complete the full reclamation plan.

Any licensing actions that are taken during the interim period, while the generic environmental impact statement is being prepared, will be subject to express conditions that currently approved waste generating processes and mill tailings management practices may be subject to review in accordance with the conclusions of the final generic statement and any related rulemaking.

The major policy issues (associated with uranium mill tailings) that remain to be resolved are those concerned primarily with the long-term management and disposal of these materials. These issues involved considerations relative to the following areas:

1. Direct Regulatory Authority Over Tailings

   Under the Atomic Energy Act, NRC has regulatory authority over uranium mill tailings while the uranium mill is in operation. However, since these tailings contain less than 0.05 percent uranium, NRC has no jurisdiction over them after the mill shuts down. For adequate long-term control, uranium mill tailings should be subject to some type of direct licensing or regulatory authority. The issues remaining to be resolved are what type of authority is needd, how it should be obtained, and who should administer it.

2. Financial Arrangements

The interim Performance Objectives require that a mill operator provide surety arrangements to assure that sufficient funds are available to carry out the tailings disposal plan. The issues that now need to be resolved are (a) what constitutes an adequate financial arrangement and (b) who should administer this financial arrangement.

3. Land Ownership and Long-Term Care

The issues to be resolved here are (a) to whom should the ownership of the land on which tailings are disposed revert and (b) who should assume the responsibility for long-term control, care, and monitoring (if necessary) of this disposal site.

The generic environmental impact statement on uranium milling will involve an analysis of the technical, legal, and financial considerations involved in each of these areas. This analysis will form the basis for the staff's recommendations to the Commission concerning the various policy options associated with the waste management of mill talings. Since all of these issues directly involve and affect the States, it is essential that the States work closely with the NRC staff in resolving these policy issues.

OTHER FUEL CYCLE FACILITIES

There are current programs at ERDA and NRC to evaluate facilities, other than mills, that previously handled radioactive material and have since been released for unrestricted use.

In June 1974, the Atomic Energy Commission (AEC) instructed its field offices to identify sites possibly contaminated with radioactivity as a result of being used for research and development activities in the early days of the Nation's atomic energy program.

Many of the sites were used more than 30 years ago as part of the World War II Manhattan Project. Others were used by the AEC from the late 1940's through the 1960's. The sites were either owned by, or under contract to, the Government; and many are presently being used for other purposes.

Prior to their release from Government control, the sites were to have been decontaminated according to health guidelines then in use. In many cases, however, the radiological records to document the extent of cleanup actions were incomplete or are presently missing.

Thus far, about 80 sites have been identified for review; of these, ERDA estimates approximately 40 may require radiation surveys by its contractors and 10 to 15 sites may require some remedial action.

Based on its knowledge of these sites, ERDA does not believe that any of them pose an immediate health and safety problem. However, some sites may contain licensable quantities of material and thus require an interface with NRC or the State to determine what course of action should be taken where questions concerning possession of this material are involved.

Because of the potential problems identified by ERDA at the former Government-owned and AEC contractor sites, NRC is committed to review the files of AEC licenses terminated prior to 1965 to assure itself that adequate documentation exists to show that the sites were properly decommissioned. Since these files number in the thousands and staff time is limited, NRC is actively seeking a contractor to perform this service. This program, hopefully, will get underway this fiscal year; and the file search will be complete by the end of next year.

Even though the Commission has acceptable guidelines for decommissioning nuclear facilities, these guidelines have not been published as regulatory guides because of the need to change them periodically to accommodate changing regulatory requirements and philosophies. Furthermore, these guidelines will continue to be evaluated and updated to accommodate problems that come to light as a result of the resurvey programs at ERDA and NRC. To further refine the requirements for decommissioning, NRC is sponsoring a study by Battelle Memorial Institute's Pacific Northwest Laboratories to determine the environmental effects, radiological effects, costs, and appropriate radioactivity limits for currently accepted methods of decommissioning fuel cycle facilities. When these studies are completed, regulatory guides will be developed in coordination with ERDA, EPA, and the States.

Also, for new major fuel cycle licenses and at the time of renewal for existing licenses, the licensee is being requested to provide decommissioning plans and financial arrangements for defraying these expenses. Additionally, the staff is exploring what statutory or regulatory changes are needed to require financial responsibility for decommissioning at the time of licensing. NRC does not plan to firm up details of financial arrangements until after the study on financial surety arrangements now being carried out as part of the GEIS on uranium milling is completed, since most of the considerations dealt with in that study will also be applicable to fuel cycle licenses. In addition, we feel that a few practical cases should be completed prior to rulemaking.

Although accurate cost estimates for correcting the problems at inactive or abandoned fuel cycle facilities are not complete, some preliminary estimates run into the millions of dollars. As most of this sum will have to be borne by the public, you can all imagine the adverse reaction as this story unfolds. in conclusion, I would like to reemphasize that as regulators, the message to us is perfectly clear--we must make the necessary statutory, regulatory, and procedural changes to prevent the creation of similar problems in the future.

SESSION: NUCLEAR MEDICINE AND RADIATION THERAPY

Moderator: *Michael Christie*, Idaho

REGULATORY PROBLEMS IN VETERINARY NUCLEAR MEDICINE
Dan Hightower, *D.V.M.*, *David M. Hood*, *D.V.M.*, *and R.D. Neff*, *Ph.D.*,
Texas A&M University

QUALITY ASSURANCE WORKSHOPS IN NUCLEAR MEDICINE
Goldie Watkins, New York State Department of Health
Richard J. Van Tuinen, Bureau of Radiological Health, FDA

COBALT-60 TELETHERAPY SURVEY
J.N. Gitlin, *D.P.H. and Donald L. Thompson*, *Ph.D.*, Bureau of Radiological Health, FDA

STATUS REPORT ON NUCLEAR PHARMACY
Jerome A. Halperin, Bureau of Drugs, FDA

SESSION: FALLOUT IN 1976

Moderator: *Edd Johnson*, Wyoming

STATUS REPORT ON THYROID BLOCKING AGENTS
Jerome A. Halperin, Bureau of Drugs, FDA

SUMMARY OF MONITORING RESULTS FROM STATE AND FEDERAL PROGRAMS
Floyd L. Galpin, Office of Radiation Programs, EPA

DISCUSSION OF FEDERAL AND STATE ACTIONS RELATED TO 1976 FALLOUT EPISODE
Thomas M. Gerusky, Pennsylvania Department of Environmental Resources
John R. Stanton, New Hampshire State Radiation Control Agency
Floyd L. Galpin, Office of Radiation Programs, EPA

RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS - NEW PROPOSED RECOMMENDATIONS
Bernard Shleien, Bureau of Radiological Health, FDA
Floyd L. Galpin, Office of Radiation Programs, EPA
John R. Stanton, New Hampshire State Department of Health and Welfare
Sherwood Davies, New York State Department of Health

SESSION: NONIONIZING ACTIVITIES

Moderator: *James C. Wynd*, Ohio

RESULTS OF THE EPA ENVIRONMENTAL RADIOFREQUENCY RADIATION MEASUREMENT PROGRAM
F.L. Galpin, *T.W. Athey*, *N.N. Hankin*, *and D.E. Janes*, U.S. Environmental Protection Agency

LASER LIGHT SHOWS - A NEW CHALLENGE
Henry P. Copeland, Georgia Department of Human Resources

CONTROL OF LASERS IN THE ENTERTAINMENT FIELD
Francis J. Bradley, New York State Department of Labor

LASER STANDARD AND RELATED BRH COMPLIANCE EXPERIENCE
Robert G. Britain, Bureau of Radiological Health, FDA

SESSION: TECHNICAL POTPOURRI II

Moderator: *Eddie S. Fuente*, Mississippi

STATUS REPORT - NRC/EPA TASK FORCE ON EMERGENCY PLANNING
Harold E. Collins, Assistant Director for Emergency Preparedness, Office of State Programs, NRC

ACTIVITIES OF THE ATOMIC INDUSTRIAL FORUM OF INTEREST TO STATE PROGRAMS
E. David Harward, Environmental Projects Manager, Atomic Industrial Forum, Inc.

SPENT FUEL STORAGE
T. Jerrell Carter, Office of Nuclear Reactor Regulation, NRC

PLENARY SESSION

Moderator: *David K. Lacker*, Texas

USE OF RADIATION IN BENIGN DISEASES
Albert W. Hilberg, M.D., Division of Medical Sciences, National Research Council, National Academy of Sciences

THYROID IRRADIATION FOLLOWUP STUDIES
Margaret H. Sloan, M.D., National Cancer Institute

ARE STATE AND FEDERAL AGENCIES MEETING TODAY'S CHALLENGES? - PART I
Robert Alvarez, Environmental Policy Center

ARE STATE AND FEDERAL AGENCIES MEETING TODAY'S CHALLENGES? - PART II
Terry R. Lash, Ph.D., Natural Resources Defense Council, Inc.

CLOSING SESSION

Moderator: *J. Dale McHard*, Oklahoma

REPORT ON RESOLUTIONS
J. Dale McHard, Chairman, Conference of Radiation Control Program Directors, Inc.

EXECUTIVE BOARD REPORT
J. Dale McHard, Chairman, Conference of Radiation Control Program Directors, Inc.

SUMMATION AND CLOSING REMARKS

Sheldon A. Schwartz, Office of State Programs, NRC

Robertson J. Augustine, Ph.D., Office of Radiation Programs, Environmental Protection Agency

James W. Miller, D.D.S., Office of Medical Affairs, Bureau of Radiological Health, FDA

J. Dale McHard, Chairman, Conference of Radiation Control Program Directors, Inc.

REGULATORY PROBLEMS IN VETERINARY NUCLEAR MEDICINE

Dan Hightower, D.V.M.
David M. Hood, D.V.M.
and
R. D. Neff, Ph.D.
Texas A&M University

(Presentation made by Dr. Hightower)

(**Editor's Note:** This presentation was prepared and edited from the authors' submitted manuscript. The speaker declined to furnish the figures cited. We regret the inconvenience to the reader.)

Over the years there have been several definitions proposed for nuclear medicine. The one I like best is incorporated in how the American Board of Nuclear Medicine described its initial examination. It is "The examination is designed to evaluate the applicant's knowledge and competence in clinical nuclear medicine, including imaging procedures, in vitro tests, in vivo function studies, and therapy, and also the related fields of medical nuclear physics, radiochemistry, radiation biology, radiation protection, nuclear medical instrumentation, radiopharmacy, and radiopharmacology." Basically, this states that nuclear medicine includes imaging, in vitro procedures, function studies, and therapy. Our definition of veterinary nuclear medicine would include all of these. In our case, one could almost add another topic and it would be research. This would be research in the facets mentioned as well as using radionuclides and radiopharmaceuticals to study other physiological phenomena. These are the things that we are doing; therefore, we have chosen to call our endeavors veterinary nuclear medicine.

Those of us working in veterinary nuclear medicine at Texas A&M University are not alone. We know that there are at least seven other colleges of veterinary medicine that have a capability or have expressed an interest and/or intention of developing same. The capability may be limited at present, but can be expected to grow. In addition, several private veterinary practitioners have made inquiries into the present state of the art. Reasons for this are probably obvious. Nuclear medical procedures are giving us clinical information that is difficult and/or impossible to get by other means. This is permitting us to do a better job for our client.

Some indication of the level of effort going on in our laboratory at the present time might be of interest. During the period of 1 January through 25 May (when these figures were assembled) we had performed 392 in vitro procedures. These were primarily T3 Uptake and T4 tests, so since there were two tests involved, this figure can actually be doubled. We have performed 37 kinetic studies; i.e., measuring cardiac output, renograms, or something of this type. We have performed 243 imaging procedures. If one looks at the rate that these are being done, it is easy to see that they are increasing. Illustrations of veterinary nuclear medicine procedures will be given below.

This week in Chicago at the Society of Nuclear Medicine Meeting, a group from Switzerland reported on bone scans in horses. They had done over 200 horses for various types of lameness. It was a very interesting talk. About 2 weeks ago, we had an occasion to be called upon because a private veterinarian, in conjunction with a radiologist, had given phosphorous-32 to a dog with polycythemia vera. This was done without proper licensure. It was reported in the newspaper and created somewhat of a stir (particularly among regulatory personnel). I do not think any great hazards were created, but I give you this as an example of the type thing that can happen. In addition to this, we were called recently by the radiological health office of a medical institution where veterinarians on their staff had treated a canine thyroid carcinoma with radioactive iodine. The question to us was when can we send the animal home?

My reason for mentioning this is to alert you to the fact that the use of radiopharmaceuticals, nuclear medicine procedures, or the establishment of veterinary nuclear medicine as a clinical speciality within the veterinary profession is going to be a fact in the very near future. The point to be made at the present time is that there is no regulation available concerning veterinary nuclear medicine. One needs to be developed without delay. This should not be a big problem, it is just one that has not been faced as yet.

The other thing that I want to point out to you is that now is the time for you to become familiar with the problems being faced in veterinary medicine. It would be preferable to have a regulation developed on a logical basis (scientific basis) rather than an emotional one. If you suddenly find out that veterinarians are using radiopharmaceuticals, it may become an emotional issue.

The last reason for this presentation is that we need your assistance. At the present time, the assistance of people in radiological safety and radiation control is needed to develop a reasonable, logical, regulation that will protect everything that needs to be protected, but will also permit the practice of veterinary nuclear medicine. As an example of this, a representative of the TAMU Radiological Health Office now spends full-time in the College of Veterinary Medicine. This arrangement has proved enlightening for both groups. The College of Veterinary Medicine now realizes more fully the many things he does to assist us, as well as more conventional duties. The Radiological Health Office has a much better appreciation of all the things going on in the various laboratories. It has certainly proved beneficial to both.

I would like to show you some scans to indicate to you the type of clinical information we are getting. Figure 1 shows a normal thyroid scan in a dog. This was done with iodine-131 and a rectilinear scanner. It shows that both glands can be easily identified. Figure 2 shows scintillation camera pictures of a dog that was presented to us with a big mass in the neck. This animal was also hypothyroid. The technetium-99m scan was equivocal since the right thyroid gland was not easily visible. The Iodine-123 scan shows that both thyroids were present and normal. Figure 3 is a normal technetium-99m scan for comparison. The parotid salivary glands are also visible and are frequently used as a landmark. It turns out this dog did have a tumor, but it was not of thyroid origin.

I thought it might be interesting to show you that this can be done in horses also. Figure 4 indicates a thyroid scan being done in a horse with the old rectilinear scanner. To indicate to you that we are a little more up-to-date now, this slide shows us imaging the thyroid in a horse with goiter. Figure 5 is a closeup picture of the enlarged thyroid, and figure 6 is the scan picture of the goiter. Figure 7 is of a cow to show the versatility of equipment and technique. There was a question in the minds of the clinical staff as to whether this was a thyroid tissue or tumor. It turned out that the thyroids were completely normal. This cow did not enter the food chain.

Figure 8 is a normal lung scan in a dog. Figure 9 shows you what we expect to see in heartworm disease in dogs. Figure 10 is a diffused metastatic lesion in the lung that was normal radiographically. This dog did go to necropsy and these lesions were confirmed at necropsy.

Figure 11 is a normal liver scan in a dog. Figure 12 is a scan of metastatic disease in a dog. This is a pancreatic carcinoma that has metastisized to the liver.

Figure 13 is a picture of a cat that had a squamous cell carcinoma in the nose. A gallium citrate scan of this cat indicated an uptake in the region of the tumor, but it also indicated metastasis to lymph nodes in the neck. These were not palpable, but they were biopsied after the scan and metastasis confirmed.

Figure 14 is a normal bone scan in a dog. Figure 15 shows metastatic lesions in the ribs. This was a very difficult case for us. There was no indication whatsoever that there were lesions in the ribs until the scan. I wanted to show you the type of scan information that we are now able to get in dogs, and the fact that this is useful to us for diagnostic and prognostic purposes.

What I want to do now is to describe to you what I think the nature of the problems that we face are and to emphasize that we need guidelines to proceed. The first thing is that we have to consider the dog or the animal as a source of radiation. At the present time, we're measuring the intensity of the radiation at the "hottest" point on the surface of the animal following administration of a radiopharmaceutical. We feel that data of this kind is absolutely necessary to provide an adequate guideline. Our current thinking is that animals should not give a radiation reading greater than 1 mR/hr at the time of discharge. Some people I have discussed this with think this is being too stringent. They feel we need to give consideration to the radioactive material being used. For instance, there is a difference in the magnitude of the problem if one is using iodine-131 for therapy or technetium-99m for diagnostic purposes. This is one facet that needs to be given some thought, and in addition, we think we need to gather additional information. We are in the process of doing this.

Another aspect of the problem that requires some consideration is the rate of excretion of the radioactive material. We cannot assure you that all of the radioactive material excreted is going to go down the drain. Some of our animals do not listen to reason concerning where they may deposit urine or feces. From a practical standpoint one can divide radiopharmaceuticals by half-life into three intervals; 1 hour to 1 day, 1 day to 8 days, and greater than 8 days. Acceptable excretion rates for discharge of the dog can then be specified for each interval. This means that this type of information must be collected also.

Another point; we think that there needs to be a release form signed at the time the dog is discharged so that the client actually has the entire procedure and necessary precautions (if any) explained to them. At the present time, we are doing this on an explanatory basis but we are not actually having a form signed.

Training requirements prior to licensure need to be examined. The NRC and other agencies have these for physicians and they are becoming stricter all the time. There is going to be a limited number of places that a veterinarian can get this proper training at the present time. This is something that is going to require some thought. Right now most veterinary nuclear medicine is in colleges and universities where there are training opportunities.

The last problem we have to solve pertains to clearance of radiopharmaceuticals by the Food and Drug Administration for use in veterinary medicine. The problem is that none of the manufacturers are willing to spend the time and effort to have these cleared because the market in veterinary medicine is so small at the present time. We have been in contact with the proper people at FDA and it would appear that a satisfactory solution can be worked out.

In conclusion and summary, let me say that I think that veterinary nuclear medicine will increase in the future. I think it will increase because the information obtained is useful in diagnosis and prognosis. The equipment is going to be very expensive, but I do not think that is going to be the determining factor. It is entirely possible that the "camera in a van" approach will be the greatest source of equipment. Once these entrepreneurs discover veterinary medicine, they will want to include veterinarians as part of their clientele. I think this is going to happen in the future. We wanted to bring you up to date on what is going on in veterinary nuclear medicine, show you the type of useful information that we are capable of getting, tell you what we think the nature of our problems is, alert you to the fact that it's coming, and ask for your assistance.

QUALITY ASSURANCE WORKSHOPS IN NUCLEAR MEDICINE

Goldie Watkins
New York State Department of Health
and
Richard J. Van Tuinen
Bureau of Radiological Health, FDA

The use of radionuclides for diagnostic purposes is one of the more rapidly growing segments of the medical market. An increase of 20-25 percent per year was reported in a 1974 survey by Frost and Sullivan, an international health care publisher. This expansion stems in part from the wide acceptance of the value of nuclear medicine procedures by the medical profession and the increasing availability of low cost radiopharmaceuticals. An additional stimulus to the growth of nuclear medicine comes from the current standard of the Joint Commission on Accreditation of Hospitals requiring hospitals of over 200 beds to provide diagnostic nuclear medicine facilities. Currently, there are nearly 3,000 hospitals plus 1000 independent clinical laboratories that provide nuclear medicine services. For patients, the BEIR report estimates that in 1980 the whole body dose from diagnostic use of radiopharmaceuticals will be 3.3 million person-rem.

The need for standards of practice that will improve the quality of medical care, as well as minimize the radiation exposure of patients and personnel, is both obvious and timely. One of the unique positive approaches for achieving this is through the implementation of a quality assurance program in nuclear medicine. This provides confidence that radiodiagnostic materials used in nuclear medicine are at a level of acceptable quality before a nuclear medicine procedure is begun. Consequently, the necessity of repeat clinical studies because of faulty instrument performance or radiopharmaceutical preparation is minimized, and, could possibly avoid an erroneous diagnosis.

Authorities having responsibility for assuring the delivery of good health care in the United States, such as the Joint Commission on Accreditation of Hospitals, the U.S. Public Health Service, and the Social Security Administration, have recognized the importance of conducting quality control procedures by requiring that they be performed, and the results recorded regularly, in support of accreditation or licensure of nuclear medicine services. States are in a position to encourage this concept either through their own regulatory programs or by certification of services under Medicare. Other Government agencies and professional organizations, such as the college of American Pathologists, the Society of Nuclear Medicine, the National Bureau of Standards, the American National Standards Institute, the American Association of Physicists in Medicine, and the Food and Drug Administration's Bureau of Radiological Health, have recognized the need for quality control test procedures in nuclear medicine and have encouraged voluntary implementation. Thus, quality assurance in nuclear medicine is important from at least two viewpoints: (1) reliability of diagnostic information and (2) legal requirements having to do with accreditation or licensure.

To facilitate the implementation of quality assurance in nuclear medicine, the Bureau of Radiological Health has initiated a short-term training program directed primarily to technologists. The program is presented in the form of workshops consisting of classroom instruction followed by demonstrations and supervised "hands on" experience in quality control test procedures. Quality assurance training programs for scintillation cameras and radiopharmaceuticals have been formed, while programs for rectilinear scanners and in vitro nuclear medicine assay are being developed.

The responsibility of the administration of each workshop is vested in a local workshop director, who has an interest in quality assurance. The director is assisted by a BRH coordinator, who guides the organization of the workshop, supplies audio-visual aids and training materials, and, if necessary, assists in workshop presentations. The assistance and participation of FDA's Regional Radiological Health Representatives and the Society of Nuclear Medicine are used in locating and coordinating workshop programs. State personnel may be involved in the workshops as faculty and directors.

Over a 3-year period, the scintillation camera quality assurance workshop has been given at 30 locations nationwide and attended by a total of 1,200 people, mainly technologists, but also physicians, physicists, radiation safety and state radiological health personnel, and manufacturers' representatives.

The classroom segment of the program provides a technical basis for understanding the elements of scintillation camera operation, the principal parameters that affect its imaging quality, materials and procedures needed for testing of imaging performance, and a guide for evaluating test results. The hands-on part of the program provides an opportunity for each participant to perform the tests on a camera similar to the one in his own facility. Each participant is given a workshop manual containing details of these aspects, as well as instructions for fabricating a bar phantom and preparing a flood phantom.

It was interesting to observe the change in attitude taking place among the participants in the three programs we sponsored in New York. Much of this change came from the influence of participants with a quality assurance program on those who did not have one. The workshop provided a forum for this informal interchange as well as the technical why's and how's for quality control.

A survey of attendees at five of the workshops was made 6 to 8 months after their participation. Approximately 68 percent of the responding facilities reported they were now following the recommended quality control program, either by modifying their ongoing program or by implementing one in conformance with the workshop. Of the remaining facilities, 30 percent reported they had at least a comparable quality control program prior to attending the workshop; and 2 percent reported they had not initiated a quality control program.

The economic impact of performing this quality control on health care delivery is more difficult to assess but some intuitive guesstimates are possible. Since the performance of quality control for a scintillation camera and logging of results takes a maximum of 15 minutes, the manpower cost, as well as cost of test items needed and prorated over a 2-year period will amount to $3.00 per day. This compares favorably with the cost of repeat studies for a variety of clinical settings and estimated repeat scan rates. In a marginal situation where no quality control exists and average technologists are employed but no resident physician, the repeat study rate, including repeat administration of a radiopharmaceutical, may be 10 percent. Assuming a typical radionuclide organ scan performed on a scintillation camera involves a charge of $100, the prorated costs of these repeat studies for a minimum workload of 10 studies per day would be $100. In a facility having minimal quality control, the repeat study rate may be 4 percent while the repeat study rate in a well-run nuclear medicine facility with an established quality control program may be 1 percent. The prorated cost of these repeat studies is $40 and $10, respectively. Obviously, quality control is an economic benefit for these situations that are possibly a representation of nuclear medicine practice. The experience of those doing quality control is that there is no increase or decrease in costs of camera service and maintenance. However, there is some indication that there is less instrument downtime and that malfunctions are less complicated to correct if a quality control program is maintained.

A workshop which we in New York are looking forward to is on Radionuclide Handling and Radiopharmaceutical Quality Assurance. Since this deals more directly with radiation safety practices, it is one in which a greater number of States might feel better prepared to sponsor. So far it has been presented six times and attended by a total of 200. The most recent program was cosponsored by the Idaho State Radiation Control Program.

This workshop program covers radionuclide generators from aspects of physical design and operation, calculation of yields and activity, and eluate contaminates. Tests of accuracy, geometry and linearity for dose calibrators are presented, while the portion on radiopharmaceuticals reviews microbiological testing, chromatography, and related tests. A discussion on radioxenon provides information on various breathing systems, collection and disposal of the gas, and patient procedures. Radiation safety emphasizes exposure control, use of syringe shields, and handling of contamination and radioactive waste. Recommendations for testing of radiopharmaceuticals and dose calibrators are provided in the workshop manual and laboratory protocols are provided separately for "hands-on" experimentation.

Other workshops for quality assurance of rectilinear scanners and in vitro uses of radionuclides are in various stages of development. The quality assurance workshop on rectilinear scanners has had three pilot programs presented and the manual is being prepared for publication. Topics included in the scanner workshop are the principals of spectrometer operation, quality control tests for scanners and film processors, and evaluation of test results. The design of a workshop on in vitro quality control procedures is under contract negotiation.

Sponsorship of these training workshops provides an opportunity for State radiological health programs to contribute to the improvement of the technical qualifications of the nuclear medicine profession. In conjunction with this is the furthering of better relations with a segment of the medical community and promotion of our objectives in minimizing radiation exposure. A videotape library covering workshop topics is being accumulated and States may also find it beneficial to view these for continuing education of their personnel.

COBALT-60 TELETHERAPY SURVEY

J. N. Gitlin, D.P.H.
and
Donald L. Thompson, Ph.D.
Bureau of Radiological Health, FDA

During the past 3 years the National Bureau of Standards (NBS) and the Bureau of Radiological Health (BRH) have been conducting a survey of Cobalt-60 teletherapy units to determine their accuracy in exposing a phantom to a prescribed dose. The purpose of this survey is to define the extent of potential problems associated with teletherapy facilities and, if possible, to identify remedial actions.

With the assistance of the Nuclear Regulatory Commission (NRC) and the States, an effort was made to identify all Cobalt-60 units in the United States. Each one was invited to participate in the survey and those that agreed were provided with a questionnaire and a set of thermoluminescent dosimeters with instructions for their exposure. The dosimeters and related information were returned to NBS for evaluation and the data were then made available to BRH for statistical analysis. It is important to note that the design of the survey includes a confidentiality guarantee, which means that none of the facilities will be identified with the results and that only statistical summaries will be released for publication.

As of May 1977, some 700 units were surveyed out of the approximately 1,000 that are licensed to administer therapy in the United States. Further, a subsample of facilities has been selected to verify the initial results and to offer nonrespondents a second opportunity to participate. Based upon our current schedule, a complete report on the results of the survey will be available by December 1977.

The principal sources of information were a questionnaire and a mailable dosimetric kit. In addition to characteristics of the unit, the questionnaire contained items related to dose calculations and the method used to determine the delivered dose. For the hospitals included in the survey, the American Hospital Association guide was used to add information, such as the number of beds, type of accreditation, and other characteristics listed in the guide.

The kit contained six dosimeters consisting of bulbs containing calcium fluoride which were encased in black polystyrene blocks. Each facility was instructed to set one dosimeter aside as a control, and irradiate the other five to a prescribed dose of 300 rads each. The dose was to be delivered to the center of the dosimeter as if it were at 1 centimeter depth in water. The completed questionnaire and exposed dosimeters were then returned to NBS for evaluation.

Out of approximately 1,000 facilities licensed to administer therapy in the United States, 20 groups of 50 each were selected at random. The size of each group was limited to accommodate the resources available for the survey. Each of the 50 facilities were contacted by NBS and invited to participate and the positive respondents were sent the survey package. Each round took approximately 6 weeks to complete. As of this date, we have completed the initial 20 rounds and are engaged in the followup survey of a subsample. This followup phase includes another invitation to nonrespondents and to varying proportions of the facilities based upon their previous ability to deliver a dose within specified limits.

It is important to note that, for practical reasons, the content of the survey was limited to only three of six areas (calibration, localization, treatment plan, mechanical, setup, and exposure). The data do reflect on the calibration of the unit at the time the survey kit was exposed. However, information was not obtained on localization of the beam and only the methods used in the dose calculation segment of the treatment plan were reported. We do not obtain information on mechanical factors nor does the questionnaire touch on setup or positioning of the patient for therapy. The values recorded on the dosimeters do provide data for which the mean can be calculated and which show the variations of the exposures administered to the five dosimeters.

The data are based upon the returns through Round No. 16, which was completed in December 1976. At that time the response rate was 65 percent which included 437 hospitals, 45 clinics, and 29 private offices. It is interesting to note that following the notice by the Nuclear Regulatory Commission that it was requesting all licensees of Cobalt-60 teletherapy units to submit their radiation output to similar scrutiny, the response rate to our survey increased substantially. The occasion for this action was the finding that the delivered dose from a medical teletherapy unit had been at variance with the prescribed dose at one location in the country. The therapy units included were almost evenly divided between those licensed by the NRC and those licensed by Agreement States. One hospital reported on four units, two reported on three units, and 29 facilities responded with reports on two units each.

If one utilizes a strict tolerance of plus or minus one rad for the calculations needed to determine the administered dose, only 25 percent of the respondents fell within these limits (Fig. 1). By using a 5 rad range, two-thirds of the respondents were within the interval, based on the 300 rad dose; while 8 percent reported values outside plus or minus 15 rads. Prior to the conduct of the survey, 11 equations were identified as being applicable to dose calculations under these conditions. During the survey, however, some different methods were reported by the responding facilities for this purpose. More surprising, many respondents submitted from two to four calculation methods for the same set of exposures, some of which disagreed. A common source of error was the use of the f-factor for tissue instead of that for water, which contributed a difference of about 2.4 rads.

25% within 1 rad

66% within 5.0 rads
18% within 5.1-10 rads
8% within 10.1-15 rads
8% outside 15.0 rads

Figure 1. Preliminary findings - exposure calculation accuracy for 300 rad dose.

Figure 2 illustrates some of the raw data used to calculate mean differences from the prescribed dose utilized in the survey. It is important to recognize that while the mean difference from 300 rads in terms of percentage was only 3.5, when one observes the individual values from the five exposed dosimeters, a range from 288 to 342 was recorded. The planned analysis of the data will include information on the distribution of values as well as the means and will attempt to interpret the implications of both on the need for a future action program.

$$\left.\begin{array}{r}342\\340\\293\\290\\288\end{array}\right\}\text{mean - 310.6}$$

3.5% mean difference
from 300 rads

Figure 2. Preliminary findings - actual readings (rads) from one set of dosimeters.

In determining the distribution of teletherapy units by the mean difference of the recorded exposures from the prescribed 300 rad dose, 83 percent fell within the arbitrary limits of plus or minus 5 percent, 13 percent were between 5 and 10, and 4 percent of the units were outside plus or minus 10 percent of the target value (Fig. 3). The intervals used here are those that have been used in the selection of the subsample for the followup phase of the survey. This phase will include all of the facilities that exposed dosimeters that varied by more than 10 percent, half of those in the marginal range of 5 to 10 percent, and 10 percent of the facilities that were in the category of 5 percent or less. We will also make a determined effort to elicit the participation of a representative sample of 10 percent of the facilities that declined the first invitation.

83% within ± 5%

13% within ± 5.1-10%

4% outside ± 10%

Figure 3. Preliminary findings - recorded exposure mean difference from 300 rads.

Our preliminary data may be compared to those derived from several other surveys. In 1970, 26 units in New York State were surveyed using mailable lithium fluoride dosimeters; 61 percent of these were found to be in error by more than 10 percent. In 1972, 18 units in Wisconsin were checked using similar methods; 17 percent of those reporting showed an error greater than 9 percent. Between 1969 and 1975, the International Atomic Energy Agency (IAEA) obtained responses from 570 facilities in different countries of which 20 percent exceeded the 10 percent error level. In its 1976 report the Radiological Physics Center surveyed 352 units. Of these, 9 percent were in error by 5 percent or more, and 3 percent of the units were outside the plus or minus 10 percent level. We also plan to obtain the results of the current NRC survey to include a comparison of data in our final report.

Assuming the preliminary findings are indicative of the final results of the survey, it is clear that a large proportion of the medical teletherapy units in the United States failed to deliver a specified prescribed dose within arbitrary limits. In an effort to identify the sources of error, we will analyze the information obtained in the survey and supplement it with the findings of others in the field. We are working closely with other Federal agencies such as the NRC and the National Cancer Institute and professional organizations, such as the American College of Radiology and the American Association of Physicists in Medicine. These groups have cooperated in the conduct of the survey and we expect to obtain their advice and participation in developing recommendations for a potential future action program.

Of the several options that are available, one includes the implementation of a voluntary program in cooperation with the States, administered by the Bureau of Radiological Health, funded by the NRC and traceable to NBS. Guidance on this program will also be influenced by the responses to the Notice of Intent to propose rules and develop guidelines for therapy equipment which was published in the FEDERAL REGISTER on March 22, 1977. The closing date for comments is July 20th, which provides sufficient time for all interested parties to make suggestions for the development of a control program. We are especially interested in the reaction of the State Program Control Directors, since any program is likely to involve your participation as well as your cooperation.

STATUS REPORT ON NUCLEAR PHARMACY

Jerome A. Halperin
Bureau of Drugs, FDA

The seventh annual meeting of this body in Hyannis, Massachusetts 2 years ago, I reported:

> "It is not the Agency's intent to regulate the practice of Nuclear Pharmacy and, as a matter of fact, there are certain prohibitions against that in the Food, Drug, and Cosmetic Act. However, there are some nuclear pharmacies which manufacture and distribute radioactive drugs in a sense that is quite different from compounding and dispensing which are traditional elements of the practice of pharmacy. The Agency is attempting to determine the interface between what is compounding and dispensing and what is manufacturing and distribution."

One might think that, given 2 years, we would have been able to define that interface and publish a final order to, in effect, "drop the other shoe."

In July 1975, we published a notice in the FEDERAL REGISTER that stated that FDA will not take regulatory action against nuclear pharmacies for failure to comply with the FD&C Act and the Public Health Service Act provided that: (1) it is a pharmacy and is in compliance with local pharmacy laws, (2) it is licensed for possession and use of radioactive materials by the Nuclear Regulatory Commission or an Agreement State, and (3) there is no need for regulatory action by FDA to safeguard the public health. We promised that we would propose final regulations to clarify our position with regard to nuclear pharmacy in the near future. Unfortunately, the problem has turned out to be considerably more complex and difficult than we had originally imagined. Proposing a final resolution to the "problem" of nuclear pharmacy has been compounded (no pun intended) by the difficulty of trying to understand what the real problems are and what appropriate solutions to them might be.

In my presentation 2 years ago, I described a public hearing that was conducted in April 1975 before our Radiopharmaceuticals Advisory Committee for the purpose of identifying the unique features of the preparation and supply of radioactive drugs by nuclear pharmacies. It was our hope that this forum would provide us with the necessary identifiers to establish that interface between pharmacy and manufacturing. While that hearing was well attended and provided much thoughtful and useful information, it really did not identify a clear difference between pharmacy and manufacturing. We appointed a Nuclear Pharmacy Subcommittee to the Radiopharmaceutical Advisory Committee, which worked very hard for a year in trying to identify the issues in the problem of nuclear pharmacy. The subcommittee reported to the full committee in April 1976. The report contains six recommendations for action by FDA including the recommendation:

> "...FDA clarify the issue of nuclear pharmacy manufacturing versus traditional pharmacy compounding with a policy statement; this statement should indicate that the same criteria will be used in making this determination for radioactive drugs as those which are used for non-radioactive drugs. This statement will also affirm that certain of the operational procedures in which some nuclear pharmacies engage are in fact manufacturing, and must be regulated as such."

While offering some useful suggestions to identify the boundary between manufacturing and traditional pharmacy the report suggests that we not consider nuclear pharmacy outside the overall context of pharmacy. Where we had been trying to consider nuclear pharmacy a unique situation, unlike "regular" pharmacy, the subcommittee, while acknowledging the uniqueness of the radioactivity of the drugs per se, believed that the basic activities of nuclear and non-nuclear pharmacies are similar and should be treated equally in any regulations. Both the public hearing and the subcommittee report were very useful in identifying a variety of problems in addition to the pharmacy-manufacturing question that relate to nuclear pharmacies and the parties at interest in the resolutions of these problems.

Perhaps the most useful forum for problem identification was here in Seattle in November 1975. Under the co-sponsorship of the Washington Radiation Control Program and the FDA Regional office, a small group of representatives from State radiation control agencies, nuclear pharmacies, FDA, professional organizations of pharmacists, and other interested parties spent 2 days discussing the problems and issues of nuclear pharmacy. This meeting did much to establish that each of the parties at interest was interested in nuclear pharmacy from a different aspect. For example, the State Boards of Pharmacy and the American Pharmaceutical Association were the primary groups interested in issues regarding professional credentialing of persons practicing nuclear pharmacy or compounding and dispensing radioactive drugs. There are both radiopharmacists and other persons, such as nuclear chemists, engaged in this practice. Similarly, the State Boards of Pharmacy and the APHA were interested in definitions of nuclear pharmacy, the physical requirements of a nuclear pharmacy and what constitutes a prescription for radioactive drugs. On the other hand, the State Radiation Control Agencies and NRC are interested in the issues of the possession, manipulation, and transfer of radioactive materials, including radioactive drugs. FDA has the primary interest in the issues of what drugs prepared and supplied by nuclear pharmacies may be new drugs and require a new drug application, or if they are being investigated for safety and effectiveness, an IND, and who is a manufacturer of radioactive drugs. The report of this meeting has been added to our growing docket of information on nuclear pharmacy. It has probably served as a stimulus to other groups to work on the issues in which they are interested.

The July 1976 edition of the Journal of Nuclear Medicine carried an editorial titled "Whither Nuclear Pharmacy?" by Drs. Ralph Robinson and Buck Rhodes of the Kansas University Medical Center. The editorial reviewed the issues and described some of the unique features of radioactive drugs, and offered several suggestions to define the interface of pharmacy and manufacturing. Let me read briefly from this editorial:

> "The Individual compounding of radiopharmaceuticals on prescription to individual patients or physicians in a single institution or family of affiliated institutions is the practice of pharmacy. In this situation, the radiopharmaceuticals prepared, whether in unit dose or multi dose vials, are still under the control of the preparing pharmacy. The central radiopharmaceuticals in bulk from raw materials is a manufacturer and should be subject to applicable FDA rules and regulations."

So far so good! This looked like a reasonable set of criteria to employ. Unfortunately, however, Robinson and Rhodes went on to state:

> "Somewhere in between these two examples falls a group of CRPs (Central Radiopharmacies) that have caused concern, especially in several of the Agreement States. Some of these CRPs probably are manufacturers. Others, although 'commercial,' are clearly engaged in the classical practice of pharmacy, compounding radiopharmaceuticals from approved ingredients on individual prescription."

We had clearly identified the poles of manufacturing versus nuclear pharmacy 2 years earlier; it is just this group of central radiopharmacies in the middle which is giving us all the concern. My personal impression is that the largest proportion of nuclear pharmacies fall into this grey area in the middle, and if we plotted this one graph, we would have a sharp peak in the center with small tails at both ends.

Robinson and Rhodes did accomplish something very useful. They articulated the issues in a journal that is read by all of the people who are intimately involved in the problem. Moreover, they encouraged their readers to work closely with their respective State Boards of Pharmacy and with the FDA to insure that regulatory actions would be designed to improve the quality of patient care, increase the efficiency of the regulatory process, and encourage development of nuclear pharmacy as a profession. I believe that their advice is being heeded. Certainly this group has exercised a leadership role in addressing some of these issues.

The Conference Task Force No. 6 on Nuclear Pharmacy, responsible for Part K of the Suggested State Regulations for the Control of Radiation, met in Rockville on April 25, 1977. In addition to representatives from State Radiation Control agencies, the meeting included participation by representatives of the National Association of Boards of Pharmacy, the Nuclear Regulatory Commission, the American Pharmaceutical Association, the Environmental Protection Agency, and three elements of FDA. I have read the report of this meeting which Lynn FitzRandolph of Arizona, the Chariman of the Task Force, kindly supplied to me. The Task Force is continuing to struggle with many of the same questions that we are struggling with, but it has made substantial progress in the issues of defining a nuclear pharmacy from the State Board of Pharmacy point of view, and defining a nuclear pharmacist from the professional credentialing point of view. The Task Force is working to prepare a set of Suggested State Regulations that will be applicable to nuclear pharmacy. I applaud these efforts and pledge my cooperation and the cooperation of the Bureau of Drugs in working with the Task Force so that we can mutually resolve the issues of importance with us.

Before it appears that FDA has done nothing on its own over these past 2 years let me hasten to assure you that such is not the case. A working meeting was held recently within the Bureau of Drugs to appraise the status of the issues of nuclear pharmacy and their policy implications. We are still limiting ourselves to two questions: (1) When is a nuclear pharmacy a drug manufacturer, and (2) When do the products of a ncuear pharmacy require an IND or NDA? The question of whether a process is one of manufacturing or the practice of pharmacy is a different question from when a product requires an NDA or an IND. They are linked, of course. We decided, however, that we would set aside, temporarily, the questions of when certain products of nuclear pharmacies require NDA's. We elected to consider nuclear pharmacy separate and apart from pharmacy as a whole and to set aside the question of whether a regulation, policy statement, or enforcement policy would be produced. We agreed to focus on the basic issue of drug manufacturing. The outcome of this meeting, and the action item that the Bureau has now been charged with producing, is a Guideline for Nuclear Pharmacy on the Issue of Drug Manufacturing. While this may not sound like an enormous accomplishment, it is at least recognition that we are making some progress. The issues are hard and complex. They are interrelated with larger issues that are also difficult and complex. I am not going to gaze into a crystal ball and predict when we will "drop the other shoe" but I am confident that we have found the foot and will now start to untie the shoe.

STATUS REPORT ON THYROID BLOCKING AGENTS

Jerome A. Halperin
Bureau of Drugs, FDA

The Department of Health, Education, and Welfare has been assigned the responsibility, by the General Services Administration, to assist State health departments and other agencies in the development of plans for the prevention of adverse effects from exposure to radiation including the use of prophylactic drugs to reduce the radiation dose to specific organs (40 FR 59494).

This directive stems, in part, from the increased number of nuclear power plants which have now begun, or are about to begin, operation, generating an increasing fraction of our electrical power. With some projections as high as 1,000 power reactors in operation by the year 2000, there is a growing apprehension on the part of the public regarding the safety of these plants. Among the concerns is the possibility, although remote, that one of these plants could suffer an accidental release of large quantities of fission products to the environment.

An important consequence of such a release is that large numbers of people may be placed at risk from exposure to these radioactive materials shortly after the release. The radioiodine constituent of these fission products poses a potentially serious hazard to the public health and safety, as it is rapidly absorbed and concentrated by the thyroid gland. Further, radioiodine exposure can occur both promptly from exposure to airborne contamination and over-prolonged periods through ingestion of comtaminated foodstuffs (especially milk) and water. Thyroid blocking has been proposed as a specific and prompt radiation countermeasure to reduce or prevent uptake of radioiodine and lower the radiation hazard to the general public at risk from exposure to offsite releases. The use of drugs to block radioiodine uptake by the thyroid is well known. A number of different chemical compounds have been used as blockers; of these, potassium iodide is the most useful. It is important to note that potassium iodide is being recommended as a prophylactic drug for use when (if) a decision is made that the use of such an agent is indicated by the nature and extent of the projected release.

The Food and Drug Administration has been working closely with the ad hoc committee on Thyroid Blocking of the National Council on Radiation Protection and Measurement to establish a dose of stable potassium iodide for thyroid blocking for which adequate evidence of safety and effectiveness exists. The NCRP recommendations, which will be published this year as NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," together with a number of other technical references will form the basis for FDA's decision to waive the requirements for clinical studies to demonstrate safety and efficacy for potassium iodide as a thyroid blocker.

Without discussing the pharmacology or biochemistry of thyroid blockers I shall summarize how we arrived at KI in doses of 130 mg (100 mg of iodide) for adults and 65 mg (50 mg of iodide) for children under 1 year of age as the drug and doses of choice. Our criteria are:

1. Effectiveness in blocking: We are seeking an agent that blocks the accumulation of radioiodine by the thyroid to a significant extent. Experiments using KI at various dose levels have shown that a blockade of greater than 95 percent of the uptake of iodine-131 is achieved with the oral administration of a single dose of 100 mg of iodide prior to exposure to iodine-131. If the drug is administered after exposure, the effectiveness of the blockade is less.

2. Speed of action: Onset of inhibition with iodide is rapid and is readily demonstrated at 30 minutes after oral administration.

3. Simplicity of administration: A 130-mg scored tablet permits a simple and easy way to administer a once a day dose of one tablet per adult and one-half tablet (which can be dissolved in milk and orange juice) for children.

4. Safety: Potassium iodide has been used for years in much larger doses, primarily as an expectorant, and for prolonged periods of time. The incidence of adverse reactions to iodide for therapeutic doses of 300 mg has been projected at 10^{-7}. A short-term administration, i.e., 7-10 days, of one-third the therapeutic dose is not believed to offer a significant risk from immediate or long-term iodide toxicity.

FDA is preparing to publish a Request for Submission of Abbreviated New Drug Applications for stable dosage forms of potassium iodide (tablets). This request, which will appear as a Notice in the FEDERAL REGISTER sometime this summer, will invite manufacturers or other interested persons to submit applications to produce and market 130-mg scored tablets of KI. The applications will require only a showing that the KI is biologically available in the formulation proposed, and full information on the manufacturing, including stability and packaging of the product. Products so approved would be labeled with full directions for use as an over-the-counter drug; i.e., no prescription required, for use as a thyroid blocking agent in the event of a nuclear emergency when directed by a competent public health authority.

Some consideration had been given to the use of a liquid form of KI, Potassium Iodide Solution, USP packaged in 1-ounce dropper bottles or in dark colored glass ampules of 130 mg of KI each as an interim method of stockpiling a supply of the drug until tablets become available. Problems regarding the lack of stability of the solution, difficulty in administering an accurate dose of the drug, and the logistics of stockpiling and distributing supplies of the drug in liquid form to large populations, especially rapidly in an emergency situation, have caused us to reject the liquid preparations as a practical alternative to a solid, stable dosage form as the long-term answer to the problem.

Once the Request for Submission of Abbreviated New Drug Applications is published, a supply of 130 mg KI tablets is not automatically assured. Given the potentially limited market for this product--we hope it will never have to be used--there may be little commercial interest in its manufacture. It is possible and likely that some manufacturer may see a market for possibly one-time sale of a large batch of tablets, or a small volume annually to assure that stocks are fresh or to supply areas around needed power plants when they begin operation. Such sales might be economically appealing, but it is also possible that others (e.g., nuclear utilities, State agencies, or the Federal Government) will have to sponsor a market. When an application is received by FDA, however, it will not require an inordinate amount of time for evaluation.

The FDA action to approve a drug for thyroid blocking for the general public in the event of a nuclear emergency will not address several important questions that should be of interest to this audience:

1. How will the drug be stockpiled or distributed to assure prompt access and administration in an emergency situation?

2. Who will give the order to employ the drug; on the basis of what evidence; and after what alternatives have been considered?

3. Will a thyroid blocker be administered to plant employees and emergency response personnel who may be occupationally exposed to radioiodine? If so, what drug and dose will be employed and upon whose authority?

These are questions that require consideration and planning. I am not sure whether they have been considered sufficiently by the NRC, utilities, NIOSH, State radiation control agencies, and health agencies. The availability of a safe and effective drug for thyroid blocking is only half of the problem. The issues of its distribution and appropriate use are the second half of the problem. I believe this group can exercise leadership in providing the answers.

SUMMARY OF MONITORING RESULTS FROM STATE AND FEDERAL PROGRAMS

Floyd L. Galpin
Office of Radiation Programs, EPA

I am very glad to be here today because there were some times last fall when I doubted I would make it this far. Just as one illustration of that, I have a copy of a mailgram here I thought I would share with you. This mailgram is signed by the Friends of the Earth, the Women's Strike for Peace, Eastern Suffolk for Safe Energy, Environmental Coalition on Nuclear Power, New York Public Interest Research Group, South Hampton Town Preservation Society, the Tuckahoe Taxpayers Association, there is about eleven signatures to this, and it is addressed to President Gerald Ford. It says, "The undersigned request that you immediately replace the EPA and ERDA officials responsibile for misleading the public on the fallout hazard from recent Chinese nuclear test. These officials failed to warn or take any action to protect the public against ingestion of hazardous radioisotopes. Both present and future generations will suffer for this irresponsibility. We urge you to appoint new officials who will place public health above political consideration."

It is really fortunate that I am here. There were times when I thought that I might be removed from office. So, I feel very lucky.

What I would like to do is to summarize the fallout data. It is more or less like trying to summarize a telephone book. There is no way a person can take all the data that all the States produced, and all the data that the Feds produced, and summarize it piece by piece. I have extracted data from States, data from what the EPA program had developed, and I have noted those places where I feel we can make a point that we can learn from. Let us take a look at it in that vein.

In figure 1, we have attempted to take the ERAMS data for the air concentrations, and with the computer make some interpolations to come up with an overall picture. Figure 1 shows the gross beta in air for the period October 1 to 9, 1976. To set the good friends in the Northwestern United States at ease, Florida had the highest throughout the whole series of actions of air concentration. I have talked this over with people in NOAA time and time again to try to come up with some meteorological rationale as to how that happened, and we cannot justify it. But it was there, it was confirmed by ERDA who also had a facility down there.

During the period from Octoter 1 to 9, we had the highest concentrations; one area in Florida was from 10 to 30 microcuries per cubic meter.

Figure 2 is for the period October 10 to 16, and we are already seeing some dropoff in terms of the levels.

In figure 3, one thing is interesting here (this is October 17 - 23); this shows the second pass. This is where Wyoming got the word that they had the highest reading for that particular set of readings. Actually, all we did was put out the numbers. But you see in that second pass that you have got some intrusion into the Western United States.

We have tried this same technique with the milk data. In figure 4 you see more of the spectrum of the milk concentrations that hit the Northeastern United States.

Let us look at the next place where radioactive material is critical, and that was in precipitation. Figure 5 is some data from Harrisburg. I think one of the significant things here in looking at the precipitation data is the continuum of microcuries per liter that existed in the precipitation showing how long it was around for precipitation. Some people had the idea that this cloud front was going to move across the United States, and once it hit the East

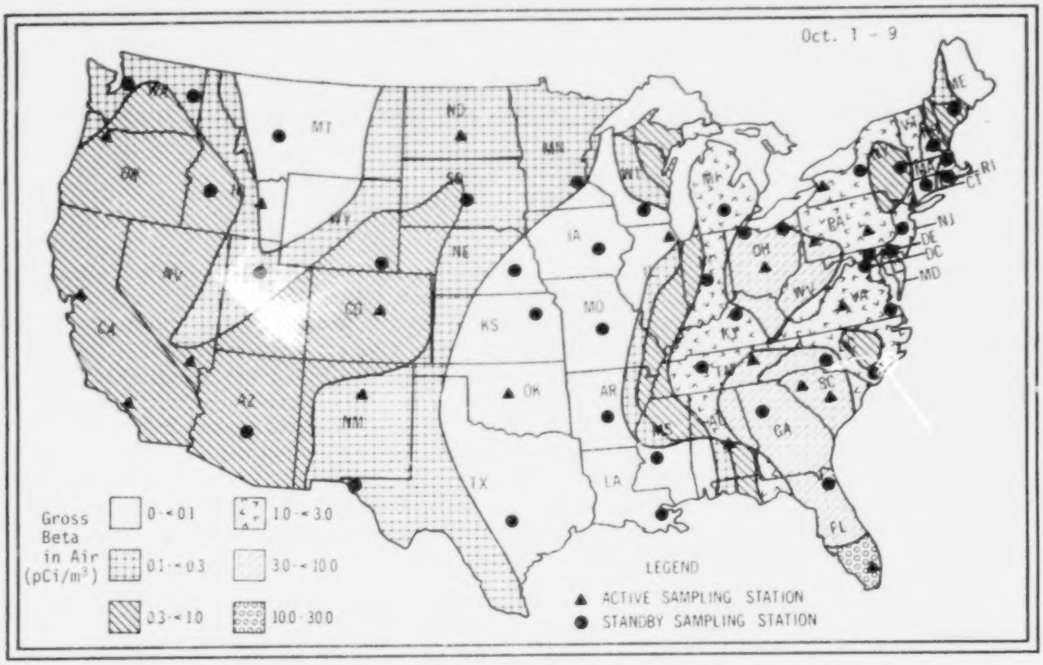

Oct. 1 - 9
WA
OR
CA
NV
ID
MT
WY
UT
CO
AZ
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MS
MI
OH
KY
TN
GA
SC
FL
WV
VA
PA
NY
VT
NH
ME
MA
RI
CT
NJ
DE
DC
MD
Gross Beta in Air (pCi/m³)
0-<0.1
0.1-<0.3
0.3-<1.0
1.0-<3.0
3.0-<10.0
10.0-30.0
LEGEND
▲ ACTIVE SAMPLING STATION
● STANDBY SAMPLING STATION

Figure 1

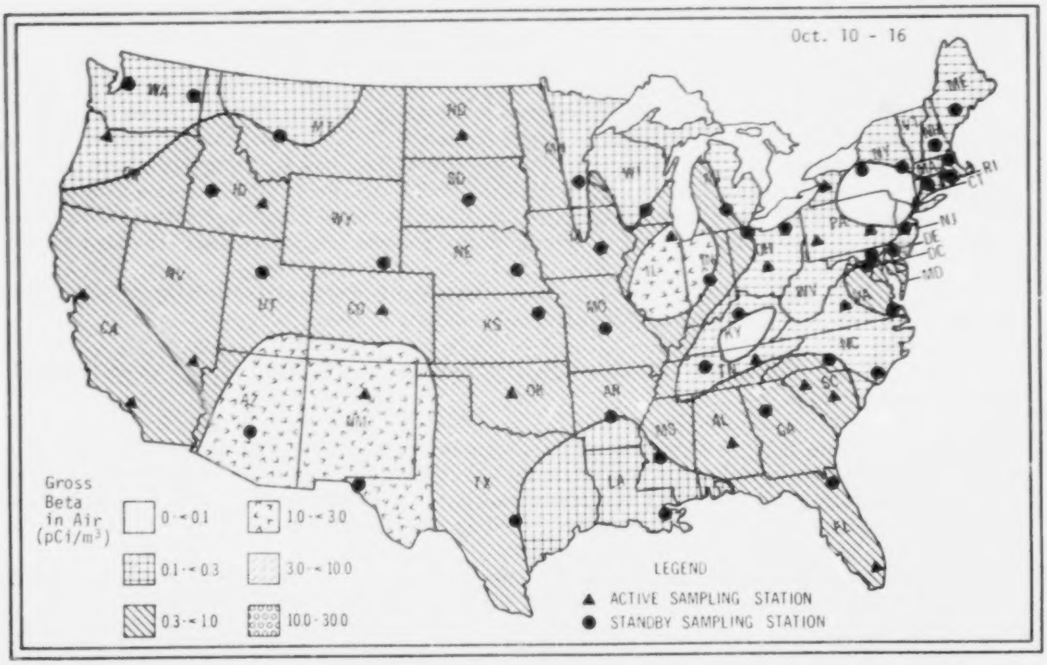

Oct. 10 - 16
WA
OR
CA
NV
ID
MT
WY
UT
CO
AZ
NM
ND
SD
NE
KS
OK
TX
MN
MO
AR
LA
WI
IL
IN
MI
MS
AL
GA
SC
NC
FL
KY
TN
OH
WV
VA
PA
NY
VT
NH
ME
MA
RI
CT
NJ
DE
DC
MD
Gross Beta in Air (pCi/m³)
0-<0.1
0.1-<0.3
0.3-<1.0
1.0-<3.0
3.0-<10.0
10.0-30.0
LEGEND
▲ ACTIVE SAMPLING STATION
● STANDBY SAMPLING STATION

Figure 2

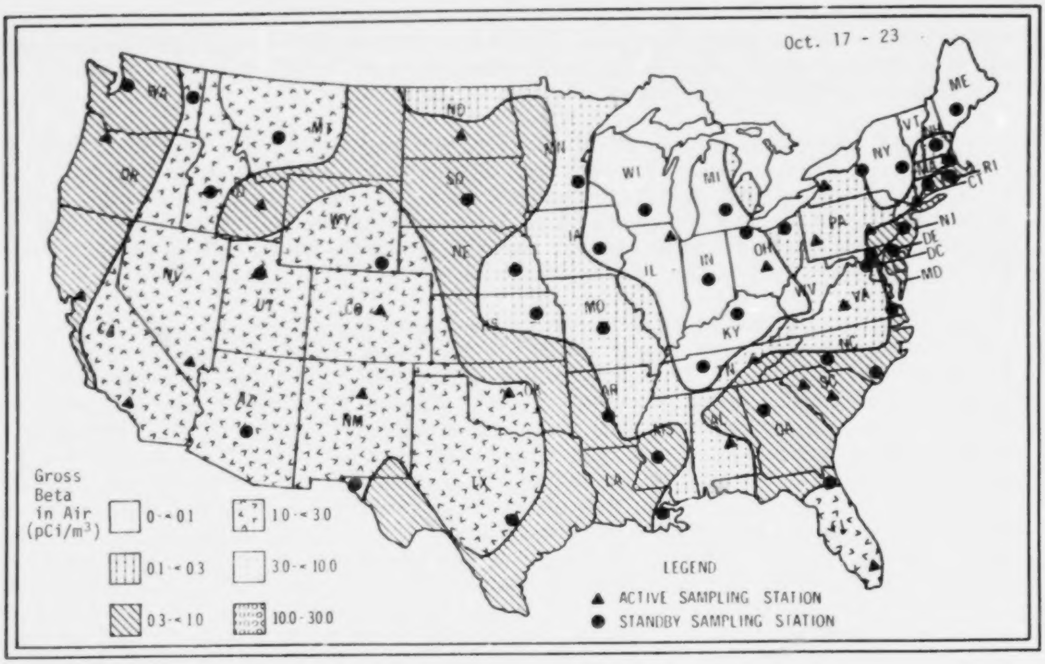

Oct. 17 - 23
Gross Beta in Air (pCi/m³)
0-<01
01-<03
03-<10
10-<30
30-<100
100-300
LEGEND
▲ ACTIVE SAMPLING STATION
● STANDBY SAMPLING STATION
WA
OR
CA
NV
ID
MT
WY
UT
CO
AZ
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MI
IN
OH
KY
TN
MS
AL
GA
FL
SC
NC
VA
WV
PA
NY
VT
ME
NJ
DE
DC
MD
CT
RI

Figure 3

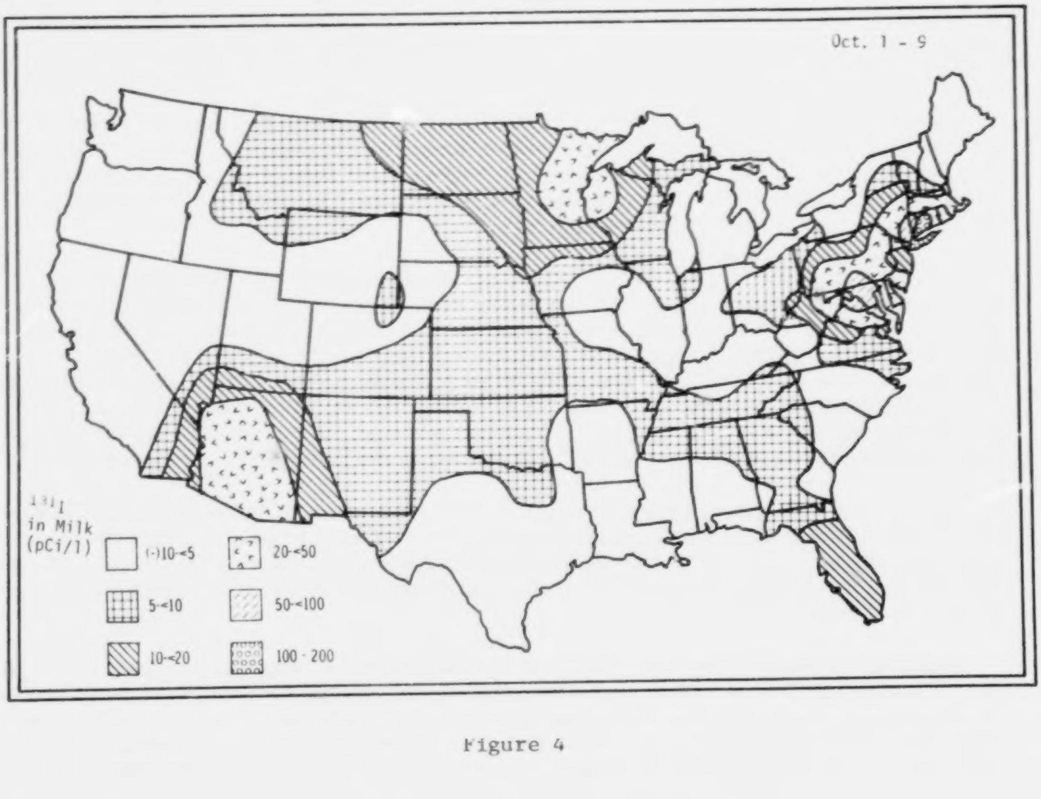

Oct. 1 - 9
¹³¹I in Milk (pCi/l)
(-)10-<5
5-<10
10-<20
20-<50
50-<100
100 - 200

Figure 4

Coast and the ocean, then it was gone. This was a problem that we had with the public perspective. If you look at this kind of information, you see the radioactivity was around for a long time and available for rain precipitation.

A lot of suggestions were made that, "Gee, you ought to be able to tell something by isotope ratios, and there shouldn't have been any doubt as to whether it was fallout or anything else." I think we can make some real attempts along these lines, but one thing I wanted to show here from the New Jersey data (Fig. 6) was that isotopic ratios were not locked in as a constant value. You had some real variations as time went along. These are precipitation samples, again, showing the iodine-131 and technetium-99^{m}.

Now, Battelle Northwest did an interesting exercise. Many times you suggest, "Well, let's take measurements on the grass and we will use that to extrapolate to a cow and then to milk and then to a human dose." Battelle Northwest tried this, in fact, they had teams that went down the West Coast and one that went down the Mississippi Valley, and one that went down the East Coast. They sampled grass on highway medians and rest areas and parks along the way, and then took this back, analyzed it, and attempted to predict from this what is going to be the dose to a thyroid from the iodine-131 in the grass. They used this relationship in figure 7 of a factor of one-tenth to go from the picocuries per gram to the picocuries per liter, and then using the .098 to go from there to a dose of a 1-year-old child. Let us look at how this turns out when you do it. If you look at what the West Coast would predict from this type of technique (Fig. 8), this shows some rather small doses of 4.2 to 1.1 of inferred thyroid dose from the grass measurements. If you go to the next one (Fig. 9), you see the Midwest; again, the levels indicated are very low all the way from North Dakota on through Texas. Now, the third one (Fig. 10), which is the first half of the East Coast, the northern half, you see that by taking this technique of going from the grass, where they got some very high readings, that they came up with some very high projected thyroid doses. In fact, thyroid doses computed from actual milk sampling, even from raw milk, were much lower in terms of an actual dose. I think the highest that I have heard about in the pasteurized milk was something like 180 microcuries per liter, which would give something about like 17 or 18 millirems. But here you see they are predicting doses of up to 185, 220 in Pennsylvania.

Figure 11 is the bottom half of the Eastern States. You see even down in Virginia, where we saw very little in actual milk, we come up there to 110 millirems to the thyroid. These kinds of doses did not manifest themselves, of course, for a number of reasons; one, it did not get into to the milk. There were not any cows in this grass that they were sampling, it is just an extrapolation that becomes very difficult.

The highest series of raw milk samples that was available in the data that I had, and I am sure there was a lot out in the country that I had not seen yet, were these for the Massachusetts area in Amhurst showing the values up to 1,300 microcuries per liter in raw milk (Fig. 12). In Connecticut (Fig. 13), the State did a composite and got 184 on October 5 at Haddam and 276 at Waterford. The utilities took individual samples at the four farms that were composited by the State. You see the ranges that were presented there, and then you see the average data of those ranges. You can see that your composite really represents, pretty well what you would have gotten from looking at the individuals and averaging them up.

Figure 14 is New Jersey data showing, at a farm there, the raw milk which is marked with the R and the pasteurized milk marked with a P. You can see how the pasteurized tracks after the raw milk. You certainly expect that that raw milk probably extends up to the upper left had they made measurements at that time, and the pasteurized milk comes tracking along after it at a lower level.

Figure 15 is some of the data that Sherwood Davies pulled together in New York. I must say that New York did a mammoth job of collecting milk. I do not know how many hundreds of samples you had there, but that was some fantastic program. The only point I want to make about this data here is to show that even for an area where we were looking at individual bulk tank routes, the tremendous range that you can get in just one area like that; 121 to 420,

HARRISBURG, PA

PRECIPITATION GROSS BETA

DATES	(pCi/l)
8/23-10/4	6,092
10/5-10/8	1,561
10/8	496
10/8-10/9	1,697
10/9	907
10/9-10/10	1,498
10/10-10/14	5,084

Figure 5

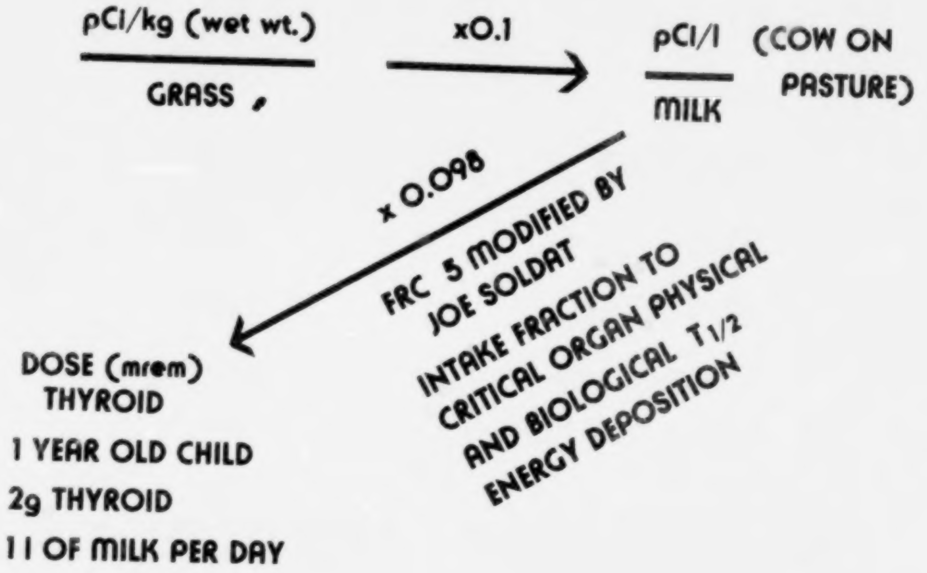
PRECIPITATION TRENTON, N.J.

DATES	$^{99}Tc^{m}$ (pCi/l)	^{131}I (pCi/l)
10/1-5	55,000	90
10/5-6	1,550	370
10/8-9	470	75
10/9-10	2,200	58

Figure 6

GRASS MEASUREMENTS – BATTELLE N.W.

^{131}I DOSE CALCULATIONS



$$\frac{\text{pCi/kg (wet wt.)}}{\text{GRASS}} \xrightarrow{\text{x}0.1} \frac{\text{pCi/l}}{\text{MILK}}$$

(COW ON PASTURE)

x 0.098

FRC 5 MODIFIED BY JOE SOLDAT

INTAKE FRACTION TO CRITICAL ORGAN PHYSICAL AND BIOLOGICAL $T_{1/2}$ ENERGY DEPOSITION

DOSE (mrem) THYROID

1 YEAR OLD CHILD

2g THYROID

1 l OF MILK PER DAY

Figure 7

GRASS MEASUREMENTS – BATTELLE N.W.

WEST COAST

STATE MAX	GRASS (pCi/kg ^{131}I)	INFERRED THYROID DOSE (mrem)
WASH.	430	4.2
OREGN.	325	3.2
CALIF.	115	1.1

Figure 8

GRASS MEASUREMENTS – BATTELLE N.W. (CON'T)

MID WEST

STATE MAX	GRASS (pCi/kg ^{131}I)	INFERRED THYROID DOSE (mrem)
N.D.	110	1.1
S.D.	215	2.1
IOWA	110	1.1
KAN.	74	.7
OKLA.	120	1.2
TEX.	45	.4

Figure 9

GRASS MEASUREMENTS – BATTELLE N.W. (CON'T)

EAST COAST

STATE MAX	GRASS (pCi/mg ^{131}I)	INFERRED THYROID DOSE (mrem)
MAINE	2,400	24
MASS.	19,000	185
N.Y.	16,000	160
N.J.	22,000	220
PENN.	17,000	169

Figure 10

GRASS MEASUREMENTS – BATTELLE N.W. (CON'T)

EAST COAST

STATE MAX	GRASS (pCi/mg ^{131}I)	INFERRED THYROID DOSE (mrem)
MD	3,600	36
VA	11,000	110
NC	4,000	40
SC	1,700	17
GA	1,700	17
FL	2,900	28

Figure 11

MASS

AMHERST RAW MILK

DATE	^{131}I (pCi/l)
10/6	1300
10/7	1000
10/8	1050
10/9	870

Figure 12

CONN RAW MILK

DATE	LOCATION	COMPOSITE (4)	INDIVIDUAL RANGE	AVG
10/5	HADDAM	184	143-248	192
10/8		135		
10/5	WATERFORD	276	38-416	245

Figure 13

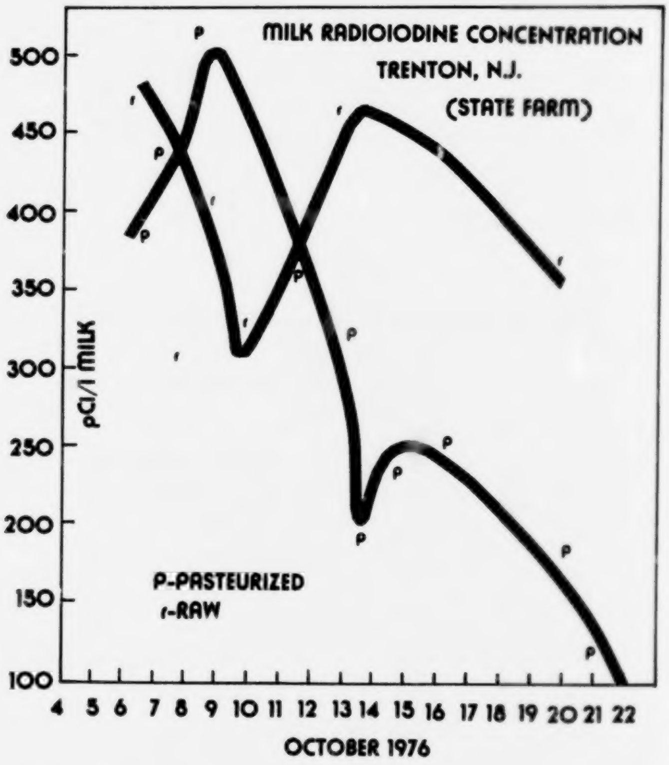


Figure 14

250 to 800. And the same type of thing shows for all of them, like in Suffolk County, 17 to 234. This stuff was really spotty.

In figure 16 Lee Bettenhausen pulled together data from a number of locations where different people did analyses in the same area; EPA, FDA, and, in this case, the Maryland Health Department. You can see the comparisons keeping in mind the ranges that existed naturally anyway. I think it is amazing that EPA and Maryland Health compare so well; it looks really almost like somebody rigged it up. You get down to the pasteurized and the raw milk, and it still looks like the same ballpark.

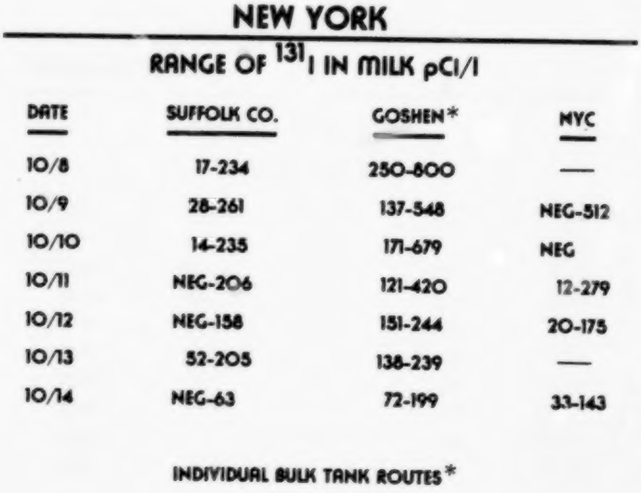
Figure 17 is the same kind of comparison in Trenton, New Jersey. EPA and the New Jersey Department, and in Pittsburgh, showing EPA and Pennsylvania Health Department. Unfortunately, the only one we got on the same day was October 22.

Figure 18 shows numbers from EPA, Pennsylvania Health, FDA, and Philadelphia. Philadelphia took many samples, and look at the ranges they have got. About all you can say there is the single composite samples did fall within the range.

Now, what does all this data mean in terms of effect? EPA broke down the population according to these age groups and integrated the milk intake for the period of time in which it had concentrations in it as well as they looked at the air and other modes (Fig. 19). The first thing we did was look at what maximum individual exposure would be.

For the highest individual doses for milk ingestion for strontium-89, Hartford got the award for 2.4 millrem to infant bone; Norfolk, Virginia for strontium-90 to infant bone; Baltimore, Maryland for thyroid of 18.4; Jackson, Mississippi for the liver of only 0.2; and for the barium, Hartford, 2.1 (Fig. 20). For air inhalation (Fig. 21), Miami would get the award with 1.8. And then air submersion, very small doses, 2.1×10^{-3} for skin; again for Miami.

What does it mean in terms of health effects? The way we calculated for the only one that made sense, the milk and the iodine was for the thyroid manrems; 67,000 (Fig. 22). Our health effects people tell us that this represents something like 4.3 excess thyroid cancers over the next 45 years. During the same time, perhaps 10 percent of those would be fatal, and during that same 45 years you would probably see from other causes something like 380,000 thyroid cancers from other causes.



NEW YORK

RANGE OF ^{131}I IN MILK pCi/l

DATE	SUFFOLK CO.	GOSHEN*	NYC
10/8	17-234	250-800	—
10/9	28-261	137-548	NEG-512
10/10	14-235	171-679	NEG
10/11	NEG-206	121-420	12-279
10/12	NEG-158	151-244	20-175
10/13	52-205	138-239	—
10/14	NEG-63	72-199	33-143

INDIVIDUAL BULK TANK ROUTES*

Figure 15

DATA COMPARISON

L.H. BETTENHAUSEN

^{131}I IN MILK (pCi/l)

BALTIMORE , MD

			MD/HEALTH	
DATE	EPA	FDA	RAW	PASTEURIZED
10/6	—	90; 190	280; 57	—
10/7	—	36; 105	360; 50	—
10/8	155	—	270	154
10/13	—	38	—	100
10/15	38	—	78	—

Figure 16

DATA COMPARISON

L. H. BETTENHAUSEN

^{131}I IN MILK (pCi/l)

TRENTON, NJ

DATE	EPA	NJ/DEP
10/22	56	80
11/1	23	25

PITTSBURGH, PA

DATE	EPA	PA/DER
10/3	-3	—
10/6	—	27
10/8	60	—
10/22	27	24

Figure 17

DATA COMPARISON

L.H. BETTENHAUSEN

^{131}I IN MILK (pCi/l)

PHILADELPHIA, PA

DATE	EPA	PA/DER	FDA	PHIL
10/4	1	<10	—	—
10/6	—	—	100	33-109
10/7	—	—	131	36-87
10/8	72	—	—	35-100
10/12	46	51	—	35-110
10/13	68	51	—	33-70
10/15	61	—	—	33-75
10/22	40	29	—	28-46
10/29	28	—	—	19-25

Figure 18

AGE GROUPS

INFANT	0-1 YEAR
CHILD	1-12 YEARS
TEENAGER	12-18 YEARS
ADULT	18 YEARS AND OVER

Figure 19

HIGHEST INDIVIDUAL DOSES (MREM)

ISOTOPES	MILK INGESTION		
^{89}Sr	HARTFORD, CT	2.4	INFANT BONE
^{90}Sr	NORFOLK, VA	1.1	INFANT BONE
^{131}I	BALTIMORE, MD	18.4	INFANT THYROID
^{137}Cs	JACKSON, MS	0.2	INFANT LIVER
^{140}Ba, ^{140}La	HARTFORD, CT	0.1	INFANT BONE

Figure 20

HIGHEST INDIVIDUAL DOSES (MREM) (CON'T)

ISOTOPES	AIR INHALATION		
ALL	MIAMI, FL	1.8	CHILD LUNG

ISOTOPES	AIR SUBMERSION		
ALL	MIAMI, FL	2.1×10^{-3}	SKIN
		6.8×10^{-4}	TOTAL BODY

Figure 21

POPULATION DOSE & IMPACT

67,850	THYROID MAN-REMS
4.3	EXCESS THYROID CANCERS
.43	EXCESS FATAL THYROID CANCERS
380,000	THYROID CANCERS OTHER CAUSES

Figure 22

DISCUSSION OF FEDERAL AND STATE ACTIONS RELATED TO 1976 FALLOUT EPISODE

Thomas M. Gerusky
Pennsylvania Department of
Environmental Resources

John R. Stanton
New Hampshire State Radiation
Control Agency

Floyd L. Galpin
Office of Radiation Programs, EPA

MR. GERUSKY: On Monday morning, October 4, 1976, I received a telephone call from the Philadelphia Electric Company's Peach Bottom Atomic Power plant that they had an external radiation contamination problem. Workers on the previous day and continuing into Monday were being checked for radioactivity contamination on a hand and shoe counter before entering the plant. This is a normal procedure since an incident that occurred a few years ago when a visitor smuggled a small quantity of uranium into the plant and then informed the press that the monitoring system was inadequate.

A check by Philadelphia Electric revealed widespread fission product contamination on the ground and other surfaces in the vicinity of the plant. The plant had been operating normally. All boiling water reactors routinely release some radioactive gases to the environment, but not the type or quantities of radioisotopes found around the plant. Automobile surfaces were checked and found to be highly contaminated. Areas outside the plant showing the highest readings were in natural water run-off areas. It had been raining for several days prior to Sunday, October 3, 1976 when the contamination was first discovered.

The Bureau had been notified by EPA the previous week that the Chinese had exploded an atmospheric nuclear device on September 26, 1976. EPA had requested that the States activate their air and rainwater sampling network. No urgency was placed on the incident since previous Chinese atmospheric tests presented no serious problems.

My first question to the Peach Bottom officials was "Could it be fallout from the recent Chinese nuclear test?" The reply was "no" because of the presence of iodine-132, an isotope not seen routinely in earlier fallout measurements.

All the nuclear plant monitoring devices were functioning and no abnormal readings were found. In my opinion, it had to be fallout, but since we had received no word from anyone that fallout had been detected, I concurred with the actions that were being undertaken by Peach Bottom; to decontaminate all shoes and vehicles and to send the construction workers home. In the meantime, we in our office and the Peach Bottom staff would attempt to determine if the radioactive contamination was widespread.

We verified rather quickly that radioactivity was present in the Harrisburg area. However, no other Federal or State agency had yet detected fallout. Our staff began a milk sampling program at the normal milk monitoring farms for Peach Bottom and Three Mile Island. The other States in the area and EPA also initiated similar studies. We immediately analyzed the EPA air samples and did not find high levels. The rainwater sample did show high levels, however.

By noon, similar findings were being reported by New Jersey. The other reactor monitoring programs were also beginning to detect radioactivity in their environment. We continued to communicate with Peach Bottom where we learned that a construction worker had cashed in on a $10 tip of the day to a local York radio station that the workers at the Peach Bottom plant were being sent home because of an accident at the plant.

Philadelphia Electric Company then made a public statement verifying the fact that environmental radioactive contamination had been found in the immediate environs of Peach Bottom.

In the meantime, our milk, water, soil, and vegetation samples were being analyzed in the laboratory, all with positive results.

On Monday afternoon, Philadelphia Electric Company put out the following press release:

> "Philadelphia Electric Company officials said today that abnormal weather conditions over the past weekend apparently caused airborne radioactivity to be deposited by the rain and stagnant air at some places on the site of the Peach Bottom nuclear power plant.
>
> "J. L. Hankins, PE vice-president for electric operations said, 'The extremely low level of the radioactivity means that there is no health hazard to the public or employees at the site.' Nevertheless, the Company has taken every precaution to assure that there will be no risk to any person. At no time did the release of radioactivity from the plant exceed allowable limits.
>
> "'For a while we had no wind to disperse the routine releases from stacks at the site and we assume some of it was dispersed on site before losing its radioactivity,' Hankins said.
>
> "However, the Pennsylvania Bureau of Radiological Health has informed PE and the Nuclear Regulatory Commission has confirmed that higher than normal levels of radiation have been detected at Harrisburg, King of Prussia, and other sampling stations in Pennsylvania. The timing, over the weekend. correlated with a recent large Chinese atmospheric nuclear bomb test. This may have been the source of the radiation.
>
> "Health physics specialists at the plant who monitor and survey the distribution of radioactivity noted above normal readings at several areas of the property. As a precautionary measure, the automobiles of all workers on the site are being washed to remove all traces of contamination.
>
> "'There has been no contamination or above normal exposure to persons,' Hankins said.
>
> "PE notified the Nuclear Regulatory Commission and Pennsylvania Bureau of Radiological Health. Both agencies will inspect the site to assure the Company complies with all recommended precautionary measures.
>
> "Operation of the plant was not affected. Peach Bottom is owned by Philadelphia Electric Company, Public Service Electric and Gas Company, Atlantic Electric Company, and Delmarva Power and Light Company. PE operates the two million kilowatt plant."

By Monday evening, it was obvious that Chinese fallout was occurring from New England through Virginia. Florida and South Carolina were also reporting increases in radioactivity measures. The telephones started to ring and we felt that it was necessary to issue a press release. I met at 8:00 a.m. the following morning with our public information officer and the Secretary, Dr. Goddard, to draft a press release as follows:

> "The Department of Environmental Resources said today that radioactive fallout from a September 26 nuclear test in the People's Republic of China has been detected in significant quantities over Pennsylvania.
>
> "The Department's Bureau of Radiological Health has increased monitoring levels of radioactive iodine-131 in milk supplies. Thomas M. Gerusky, Director of the Bureau of Radiological Health, said radioactive iodine is a very significant isotope and is rapidly taken up by dairy cattle and concentrated in milk.

"Gerusky said he will be consulting with the Pennsylvania Department of Agriculture and the U.S. Environmental Protection Agency to determine if any protective actions need to be taken.

"Because of the heavy rainfalls recently in the Southeastern portion of the Commonwealth, the fallout was found on the ground and in precipitation samples rather than in air samples as is usually the case. As a result, it is difficult to determine exact levels of radioactivity, but Gerusky said it was higher on the ground than had been detected in Pennsylvania for many years.

"He cautioned those persons taking vegetables from home gardens to wash the items carefully before eating them.

"Philadelphia Electric Company's radiation monitoring program at its Peach Bottom nuclear power station in York County first detected the fallout, Gerusky said. Analysis of samples in Harrisburg verified that significant levels had occurred, most probably a function of the recent rains which trapped the radioactive particles and deposited them on the ground.

"The test at the Lop Nor testing site in western China occurred on September 26 and the U.S. Environmental Protection Agency had projected fallout would be over Pennsylvania by Sunday, October 3.

"The Peach Bottom monitors detected the fallout on Sunday and reported the condition to the State officials on Monday, October 4.

"The environmental radiation monitoring program at the Three Mile Island nuclear power station at Middletown, near Harrisburg, verified the Philadelphia Electric and DER readings.

"Gerusky said additional information will be given to the public by the Department as it becomes available."

The earlier reply concerning iodine-132 in the radioactivity samples had us slightly baffled at first, because iodine-132 was not routinely detected in previous fallout situations. Since the high fallout days of the early 1960's, many advances in technology had occurred. Now, in the mid-seventies it is possible to use a Ge-Li detector and separate specific isotopes by their individual sharp gamma peaks. In earlier detectors, iodine-132 adds to the cesium-137 peak and was counted as cesium. Everyone with the new detectors was finding iodine-132. Mystery solved!

Before the press release was issued, the phones in the Bureau were all ringing. That whole day was spent answering press inquiries. That evening I was interviewed on national ABC television by Barbara Walters and Harry Reasoner. The next day, all calls were referred to our Public Information Office, so that we could do the work that we were supposed to be doing.

The press reaction was totally unanticipated. As an example, I went to work Tuesday morning without a tie and in a leisure suit which was too small.

We had to set up two-way radio communication with our lab because the phone lines were still tied up.

Besides the public relations fiasco, we had serious problems with establishing action levels for a variety of response situations. Although our main concern was milk supplies and iodine-131 contamination, the fallout was so intense that significant levels were found on the ground. As an example, here at Penn State, the nuclear engineering students went out and wiped off the surfaces of automobiles in the parking lot and then analyzed the radioactivity content.

They concluded that they would be required to have a Nuclear Regulatory Commission license to possess the quantities of certain of the fallout isotopes.

I do not recall a similar situation occurring since I joined the State radiation protection program in 1961. But something similar did occur from a United States atmospheric test in Nevada in 1958 when I was a health physicist at the "hot laboratory" at Brookhaven National Laboratory on Long Island. We had established allowable floor and shoe contamination limits in the high level areas of the building. When workers showed up at 8:30 for the daily shift, their shoes were setting off alarms on the hand and shoe counter on their way into the facility. A contamination survey of the whole building revealed no widespread contamination, but we were able to find footprints. Again, we checked the cars in the parking lots and found that they were highly contaminated. In effect, it was hotter outside the building than we would allow inside the building.

Back to the 1976 problem, we were also sampling cisterns, drinking water supplies, vegetables, air, rain, and milk. The levels of radioactivity in cistern water was easily detected. It was interesting to find out that many people still use cistern water for their drinking water, some with no filtration whatsoever.

We sampled milk from goats and found about a factor of 2 higher level in goat milk supplies. This could be due to the goats being on full pasture feed, while the cattle were on partial stored feed, or maybe the goats eat more than the cows.

MR. STANTON: What was done? Why was it done? What lessons were learned? A bit of history first. The news of the October episode broke while one-half of our agency was in Bethesda at the NRC Agreement States meeting. This set the stage for the, all too usual, management by crisis posture to be assumed on the home front. All stops were pulled; all outgoing radiological health activities were suspended in order to discover the unseen enemy.

For an agency as small as ours, the effort was monumental, at the time politically expedient, but in retrospect probably radiologically unnecessary. Four precipitation sampling stations were set up (notwithstanding a prediction of sunny skies and a near zero probability of rain for the next few days); 2 pressurized ion chamber instruments were frantically moved from place to place (perhaps on the theory that the more expensive the instrumentation, the better the results - no matter what); 4 milk sampling stations were reactivated; and 28 of the State's Air Pollution Control Agency's air particulate samplers were given double duty as fallout monitors.

What sort of information was obtained from this hastily assembled monitoring program? Beginning with milk, perhaps the item of worst concern, for 12 samples taken during the period from October 8 through 12, concentrations of iodine-131 varied from 80 to 460 picocuries per liter. Most of the analyses were done through the courtesy of FDA's Winchester Engineering and Analytical Center in Winchester, Massachusetts. Fewer samples were taken during the November episode for a reason that I will discuss in a moment.

For the October episode the weather forecast proved accurate and robbed us of any chance to obtain deposition data by precipitation. Rain did occur during the November episode, however. Deposition was in the order of 10 picocuries per square meter--an order of magnitude between 1962 and 1972 data.

The borrowed air particulate sampling network proved to be most valuable. Gross beta counting of many glass fiber filters is considerably simpler and quicker than radioiodine analysis of many milk samples. So the air particulate sampling network can be used as a screening method to determine where any concentrated milk sampling should be done, or indeed if it should be done at all. However, as high air concentrations do not necessarily produce high depositions, it is also advisable to supplement this program with one which monitors dry and wet deposition.

Figure 1 shows the "background" condition on October 3; figure 2 depicts the October 9 condition. Isoconcentration lines directed the milk sampling effort to the southeastern portion of the State. Figures 3 and 4 similarly show results of the November occurrence.

The lessons learned were that help can come from hither to unthought of sources and that any future episodes can be handled with less unnecessary expenditures of effort.

But these were not the only lessons learned. I would like to quote a portion of an article that appeared in a New Hampshire newspaper on November 22, 1976--sandwiched between paragraphs of an otherwise factual AP release. It says, in part: "The eastbound cloud of radioactive fallout from the Chinese nuclear testing was not expected to be dangerous to New Hampshire, but was monitored, according to (name withheld), State (name withheld), agency director (name withheld) said today the levels measured in New Hampshire were 'very, very low.' He said the top reading was 0.2 R per hour. He further described a dangerous level of radiation as 100 R per hour." Upon reading that, I immediately jumped into my lead lined wet suit, drove to Montreal for the weekend, and vowed never again to worry about 100,000 picocuries of iodine-131 in a liter of milk.

MR. GALPIN: Let me just run down through some of the chronology and a little bit of afterthought. Hindsight is a beautiful thing. I guess I would quote Maggie Reilly from very early in the game who indicated that, in the case of Pennsylvania, if it depended upon air measurements to learn to do anything, why it would have gone right by the board. And this was kind of the state that we were in relation to ERAM. The only thing that we had any quick data on was air measurements, and they did just not tell the story. They gave an idication of where material might be, but in terms of what really happened in terms of rain out, it did not tell the story at all.

One of the things that Charley Porter is looking at after the fact is can we do any field screening relative to precipitation. Maybe this might help us, but certainly the first data I would think, in any instance like this, is going to have to come from States that are on the line. One error, I guess, that I would see as a hindsight that we might have done differently, was to issue an initial press release about September 29. ERDA notified us September 27 about the shot, the press release was made that the shot had occurred. We turned on the ERAM station as near as I can tell by September 30th; the standby stations had been brought on line. Granted, there were some gaps. We did not make press releases about turning those stations on. It was a deliberate decision. From past tests we had seen so little, the probability of a low-level atmospheric air mass that was contaminated interacting with rain was not a high probability. NOAA was trying to come up with the number just as to how high that probability is and how well they can predict that type of thing in the future. We did not make a press release. And I guess one type of thing I would like to get from the States is by making such a press release, would we have eased problems or would we have made more problems?

Just in terms of a very brief rundown of chronology, ERDA notified us on September 27 of the test. We got the first NOAA cloud trajectory condition on September 28. On September 29, we started to activate the standby ERAM stations. As I say, as near as I could tell, by September 30th they were all activated. Tom Gerusky has pretty well indicated the immediate actions that followed up from there starting with October 4th. By the way, October 4th we did take a nationwide milk sample which turned out for pasteurized milk to be too early because it did not show the results. From there on, things went from bad to worse for a period of time. I think all of us, certainly including the EPA, had not realized what I think has been a real change in public perspective. Those of us who lived through the 1960's (I was with a State agency at that time and remembered the kind of public interest that existed), one would have to say that for the relative levels, public perception has definitely changed since that time, and I think that is something we have got to plug into our cognizance; that is, how we will conduct our activities.

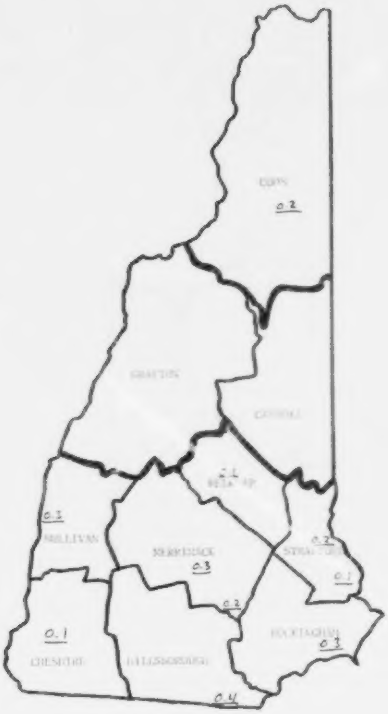

COOS
0.2
GRAFTON
CARROLL
2.1
BELKNAP
0.2
SULLIVAN
MERRIMACK
0.3
STRAFFORD
0.2
0.1
0.2
0.1
CHESHIRE
HILLSBOROUGH
ROCKINGHAM
0.3
0.4

Figure 1. Air particulate gross β (pCi/m^3) - 10/3/76.

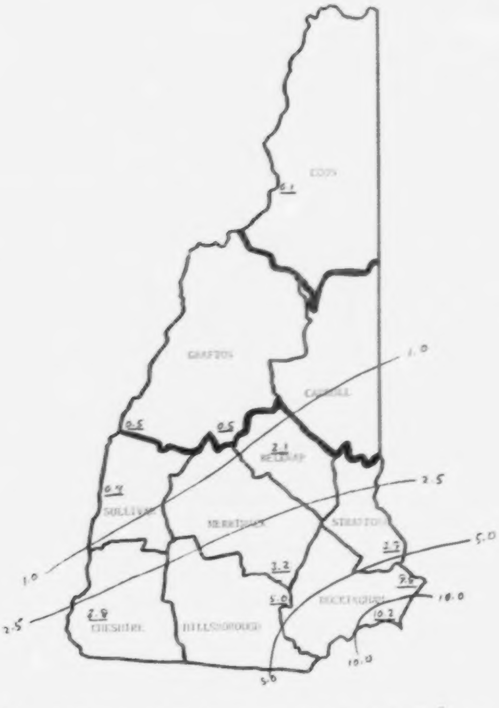

COOS
0.1
GRAFTON
CARROLL
1.0
0.5
0.5
2.1
BELKNAP
2.5
SULLIVAN
MERRIMACK
STRAFFORD
5.0
2.7
1.0
3.2
7.6
2.5
5.0
10.0
ROCKINGHAM
2.8
CHESHIRE
HILLSBOROUGH
10.2
10.0
5.0

Figure 2. Air particulate gross β (pCi/m^3) - 10/9/76.

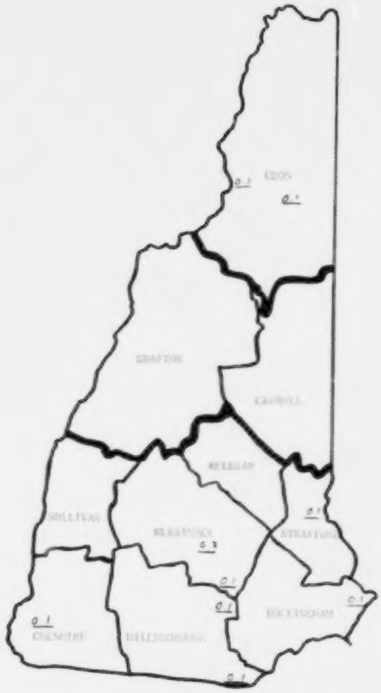

0.1
COOS
0.1
GRAFTON
CARROLL
BELKNAP
SULLIVAN
MERRIMACK
0.3
0.1
STRAFFORD
0.1
0.1
0.1
ROCKINGHAM
0.1
CHESHIRE
HILLSBOROUGH
0.1

Figure 3. Air particulate gross β (pCi/m^3) - 11/11-76.

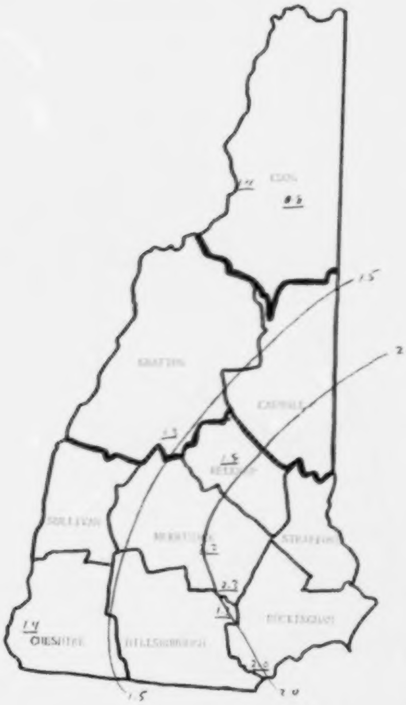

1.4
COOS
0.6
1.5
2.0
GRAFTON
CARROLL
1.5
1.6
BELKNAP
SULLIVAN
MERRIMACK
STRAFFORD
2.2
2.3
1.7
ROCKINGHAM
1.4
CHESHIRE
HILLSBOROUGH
2.0
1.5
2.0

Figure 4. Air particulate gross β (pCi/m^3) - 11/26/76.

I am going to quit there. One thing I would like to determine is when we do activate that system, that ERAMS; is there a time that we ought to notify the public that we are doing so or would we be better off not doing it?

DISCUSSION

UNIDENTIFIED SPEAKER: I was curious to know whether or not there was any degree of analysis done by ERDA or the military and whether that information is shared with ERDA and EPA and that will be made known to the States.

MR. GALPIN: There was information available both in terms of the Air Sampling as well as some degree of analysis. One thing in the nonclassified realm that I can tell you that there are very strong indications that the shot that occurred in September was a dud; in other words, that it was intended to be a fusion weapon with a fission trigger, and all that went off was the fission trigger. They obviously repaired that, come November. In a way it was a blessing in that by having that higher yield weapon in November, it took most of the material up through the troposphere and therefore it was unavailable to turbulent wind and to rain.

UNIDENTIFIED SPEAKER: But was the degree of analysis that was provided to EPA shared with the States as soon as you got it . was it shared with you to start with?

MR. GALPIN: We do not have a detailed breakdown of the isotopes, but it came after all this had gone by when I got that information.

UNIDENTIFIED SPEAKER: It would seem to me that that would be the first step.

MR. GALPIN: The first step we got was the fact that they had seen measurements in Japan that were elevated air. We did not have any rain out problems there. A coupling of Air Force data and NOAA's predictions is what gave us ideas of measurements as to where the cloud was, but we did not have specific isotopes, if that is what you mean by degree.

UNIDENTIFIED SPEAKER: I was just curious because it seems to me, just for military strategic purposes, that the Air Force would be involved and would want to know to the exact degree the composition of the degree of that cloud just to know what kind of weapon it was. That information, in part, should be shared ahead of time with the Federal agencies, who, in turn, could share that with the State programs to at least know what to expect.

MR. GALPIN: Well, we got those measurements. As we indicated, the airborne measurements really did not help us any because of the rain out situation, and we would not expect dry fallout, if you have gone back to our calculations of any of the Chinese tests, to be a problem in any case. So, it is an extrapolation that just does not come through.

RADIOACTIVE CONTAMINATION OF HUMAN FOOD AND ANIMAL FEEDS - NEW PROPOSED RECOMMENDATIONS

Bernard Shleien
Bureau of Radiological Health, FDA

Floyd L. Galpin
Office of Radiation Programs, EPA

John R. Stanton
New Hampshire State Department of Health and Welfare

Sherwood Davies
New York State Department of Health

DR. SHLEIEN: We sent out the first draft of the proposed Protective Action Guides on December 7th, 1976, to all State radiological health programs and interested Federal agencies involved in emergency radiological response. We received two dozen responses and over 100 pages of comments.

The first point that many reviewers commented on was the problem of HEW and EPA cooperation. Many reviewers indicated that there appeared to be an overlapping of responsibilities that could lead to a duplication of effort and difficulty in the formulation of guidelines. The difficulty itself is in disentangling the responsibilities that are inherent in the interagency agreements. For example, the agreement says that EPA is responsible for the establishment of general Protective Action Guides--on the other hand, it also states that HEW is responsible for issuance of guidance on appropriate action necessary for evaluating and preventing radioactive contamination to food and animal feeds and control of such products should they become contaminated. Most of the reviewers recognized that setting of specific guidance for foods was within the purview of FDA. The general consensus of the reviewers on this particular problem was that there was a need for cooperation and that Federal recommendations from different agencies should be compatible.

Correspondence between the Bureau of Radiological Health and the Bureau of Foods, FDA and the Deputy Assistant Administrator for Radiation Programs, EPA, has led to an appointment of an official EPA liaison to assure that there is a free exchange of information and opinions. Consequently, I think that the cooperation between EPA and FDA has been very good.

The second major question raised by the reviewers concerned the Delany Amendment; that is, what is the relevance of the Delany amendment to the radioactive contamination of food under accidental conditions? In my opinion, a Notice of Proposed Rule Making in the FEDERAL REGISTER (39 FR 42743) clarifies this problem. I am going to read the following portion, which I think is pertinent to the PAG's for the accidental radioactive contamination of food. I quote, "The definition of food additive established in Section 201(S) of the Act," the FD&C Act, "is not limited to intentional additives." The language in Section 201S of the Act includes any food substance and excludes only those substances which cannot reasonably be expected to become a component of the food. The statutory definition thus includes what are referred to as incidental additives as well as intentional additives. Any added poisonous or deleterious substance in food, unless accidental or unforeseeable," repeat, "unless accidental or unforeseeable or specifically exempted by Section 201(S) of the Act is a food additive." In my opinion, the conditions under which the PAG's will be employed are limited to the accidental introduction of radioactive contaminants. Radioactivity introduced under these conditions cannot be considered a food additive and therefore is not subject to the Delany Amendment.

Another comment that at least three or four reviewers raised is on the following subject: The controversy is over the blending and use of contaminated food. Several commentators questioned whether one could mix contaminated milk with uncontaminated milk or vice versa, or use contaminated products as food for other animals.

It is a long standing FDA policy not to permit the blending of contaminated products in noncontaminated products.

One comment raised the problem of the appropriate group to be used as the critical segment of the population. The commentor suggested that the fetus should be used as the critical segment of the population rather than children less than 1 year of age for iodine-131 in milk. This problem has been investigated and evaluated by several investigators. The conclusion is that newborn infants and not the fetus have the highest iodine-131 intake per gram of thyroid tissue, and, hence, this group comprises the critical segment of the population.

I think one of the larger problems we had concerned the Alert PAG as defined in the original draft. Comments were received stating that we did not recommend appropriate actions at the Alert PAG level. That is true. Secondly, the informational and administrative actions that were suggested in the draft recommendations are covered by standards and regulations of other Federal agencies; this is also true. The one action we suggested was control of the source. This action is not within the purview of FDA; also true. Finally, that sampling and analysis at the very low Alert PAG level are difficult and expensive. Considering all these comments, we have decided to drop the Alert PAG.

I think another important problem that was brought up in the first draft and not solved, is the problem of multiple events. The draft did not adequately eliminate the possibility that the projected dose associated with a specific PAG could be exceeded by a series of multiple events, each one of which alone would not exceed the PAG. A possible solution is to express radioactivity in foods in terms of total intake at which the projected dose would be equal to or exceed the PAG. In the initial draft, we expressed radioactivity levels in terms of concentration per unit intake rather than in terms of total intake. We will continue to do that, but in addition we will add numerical limits for total intake.

Some other major changes that will be made prior to publishing the proposed recommendations in the FEDERAL REGISTER concern the updating of the metabolic models employed. Several of the models went back to old FRC days. There are new metabolic models available, some using MIRD information, and we will use these newer models.

Another major change is that we will employ an entirely new agricultural transfer model that will reflect U.S. dairy practice. The initial draft is based on classical studies--they are British--and our experience in the United States relative to the intake in terms of feed per cow is different.

The third major change concerns the rationale upon which we will base the numbers. We intend to do three types of analyses. In the initial draft, we did a cost/benefit study. That is being revised with new information that we have received from the Department of Agriculture. It gives us some idea of the availability of stored feed and powdered milk. We have to perform a comparative risk analysis, a cost effectiveness analysis and a cost-benefit analysis to provide the rationale upon which we can base a rationale for setting the PAG's. In cooperation with NRC, we hope to have computer models for a PWR 7 and PWR 5 accident in the northeastern United States. We will be using the computer models that have been generated for the Rassmusen Report. We can use these models to interdict the milk supply at any PAG level we wish to set. We will arbitrarily set six levels from 0.5 rem thyroid dose to 60 rem. The model will give us the number of man-rems we can save at these various levels of interdiction and the cost in terms of agricultural losses.

These are the main points raised by the comments received on the initial draft. It took us several months to go through them. Many of them are editorial. We did our best to respond.

MR. GALPIN: I am not going to say anything except that we are working very closely with FDA. We agree with all those commentors that we are going to make this one case where the Feds are together. We both have areas of responsibility here. We plan to work so closely that there would not be any differences at the time that these come out in terms of interstate commerce. We will be able to pick up the same package and use it in our Federal Guidance Rule.

DR. SHLEIEN: We are going to issue this guidance under the Public Health Service Act which permits the FDA to issue recommendations to State and local governments. They will not be codified, they will be recommended to the State and local government; recommended for implementation.

MR. STANTON: As we are all well aware, the wait for Federal guidance on Protective Action Guides and protective actions for contaminated milk has been a long one. Yet it was a wait we all had to be willing to suffer. The perennial request seemed adequate because of the lack of contaminating events. The Peoples Republic of China changed all that last fall.

Following the October occurrence, Dr. Leonard Solon--who is not here to defend himself--from New York City wrote to the regional office of the EPA expressing his concern over EPA's use of certain portions of FRC Report No. 5 as the essential basis for protective action recommendations, in particular the recommendation that the point at which infants and pregnant women should be told to discontinue the use of fresh milk was when the concentration of iodine-131 was 4,200 picocuries per liter. Dr. Solon's concern was that the dose to the smaller fetal thyroid may be of an order of magnitude higher than that of the infant and that it would be prudent to consider reducing the PAG to a nominal 400 picocuries per liter.

His concerns were answered by EPA in late November. Briefly, it was pointed out that the 4,200 number was already a conservative lowering of the concentration for the real, 10 rad PAG's specified in FRC 5 and, further, that fetuses in pregnant women would not be the critical sector--as Bernie has already told us--of the population at risk unless these women drank 3 to 7 liters of milk per day.

Dr. Solon wished to share his concerns and EPA's reply with the milk producing States in New England and New York. Certain of the New England States had, in recent weeks--recent up to that time at least--exhibited their conservativism by "ordering" milk herds onto stored feed. Obviously, here was a friendly forum for Len. At Dr. Solon's request, a special meeting of the New England Radiological Health Committee was called in early December with a primary objective of arriving at some milk numbers with which all of us in the Northeast could live. The PAG's and associated PA's finally agreed upon were: 400 picocuries per liter--recommend against consumption by pregnant women and children up to 1 year; 4,000 picocuries per liter--recommend against consumption by the general population. I might add that this was not a unanimous decision. The State of Maine replied that it would probably not consider any protective action until a concentration of 60,000 picocuries per liter was reached.

The same December meeting was attended by Dr. Shleien, armed with the draft proposed response recommendations, which for similar protective actions suggest a PAG in the range of 8,000 picocuries per liter. Just a word or two on the proposed response recommendation. I personally think that it and the supporting documentation are well done and of considerable value to us in the States. How often do we complain about lack of guidance from Federal agencies for one problem or another, only to categorically reject the guidance when it finally does arrive? The numbers may be debatable, yet they are a point from which to debate. The cost analysis may not be complete, yet it is a model with which to continue. The analysis method may not be all to our likings, yet it is a better collection in a small package than we have ever had in the past. For those of you who have not commented on the draft, I urge you to do so when the second draft comes out, certainly when it finally gets printed in the FEDERAL REGISTER.

Finally, a real concern. Let us consider for a moment the single protective action of recommending the removal of milk herds from pasturage. We have heard guides for this action, the high and low of which are separated by a factor of 150. Have we all really considered the consequences of such a recommendation, the socio-economic as well as the radiological? Have we all considered the magnitude of the problem? Well, at least one of our members did and, at this time, I would like to call on Sherwood Davies of New York State and ask him to share his observations with you.

MR. DAVIES: I think what precipitated my discussion with the New England State Radiological Health staff is the differences in the New England PAG's and our PAG's. They are quite different. Other States also use different PAG's. We do need a uniformly accepted PAG.

Figure 1 shows the buildup of iodine-131 in milk following a single deposition. And as you will note, the iodine concentration peaks in 2 to 3 days showing a rather rapid buildup. About 12 hours after the deposition, we find measurable amounts of iodine-131 in milk. The apparent half life in milk is about 5 to 7 days after the peak is reached compared to a physical half life of 8.3 days. If we remove cattle from pasture within 24 hours, the projected dose to the population is minimized. A delay of 48 to 72 hours would result in greater doses to the population. We have a time framework of 6 to 8 hours if we want to take the most effective preventive action to minimize population exposure. Otherwise, contaminated milk entering the food chain presents greater problems of surveillance and control.

In figure 2, I have assumed a 100-curie iodine-131 release in southern Connecticut. The 100-curie release may result in measurable iodine-131 levels in milk but within the Federal Radiation Council PAG's. Iodine-131 in milk may be found at a distance of 60 or more miles from the release. This includes a substantial part of Connecticut. About 390,000 quarts of milk per day is produced in the area of Connecticut that may have iodine-131 concentrations ranging from 100 to 5,000 pCi/liter. The 75,000 quarts of milk per day produced in a part of Massachusetts may have iodine-131 concentrations ranging from 30 to 1,000 pCi/liter. What would be the applicable milk or food PAG's that States would use in event of an accidental release of 100 Curies of iodine-131?

A PAG is a speed limit. We can adopt a speed limit lower than the recommended FRC PAG's, but are we prepared to enforce the speed limit that we adopt?

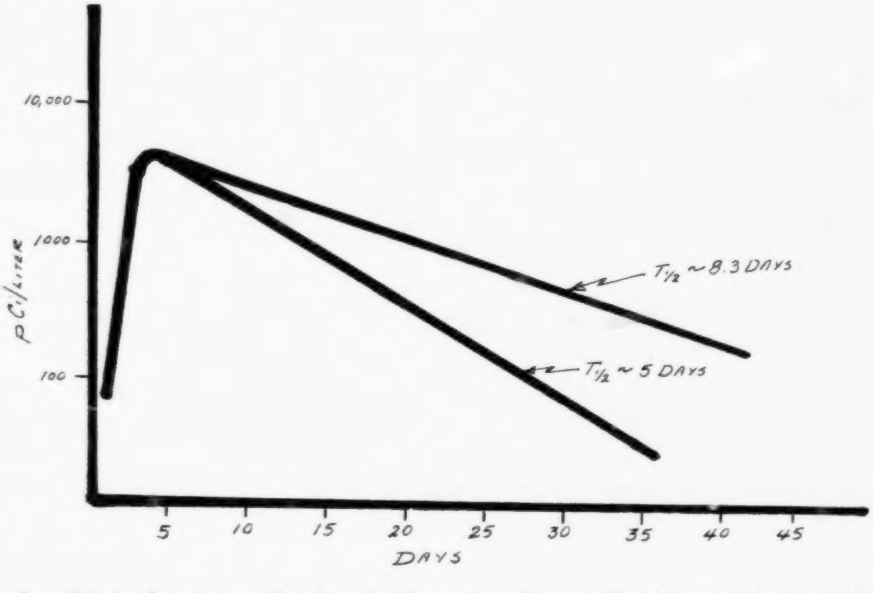
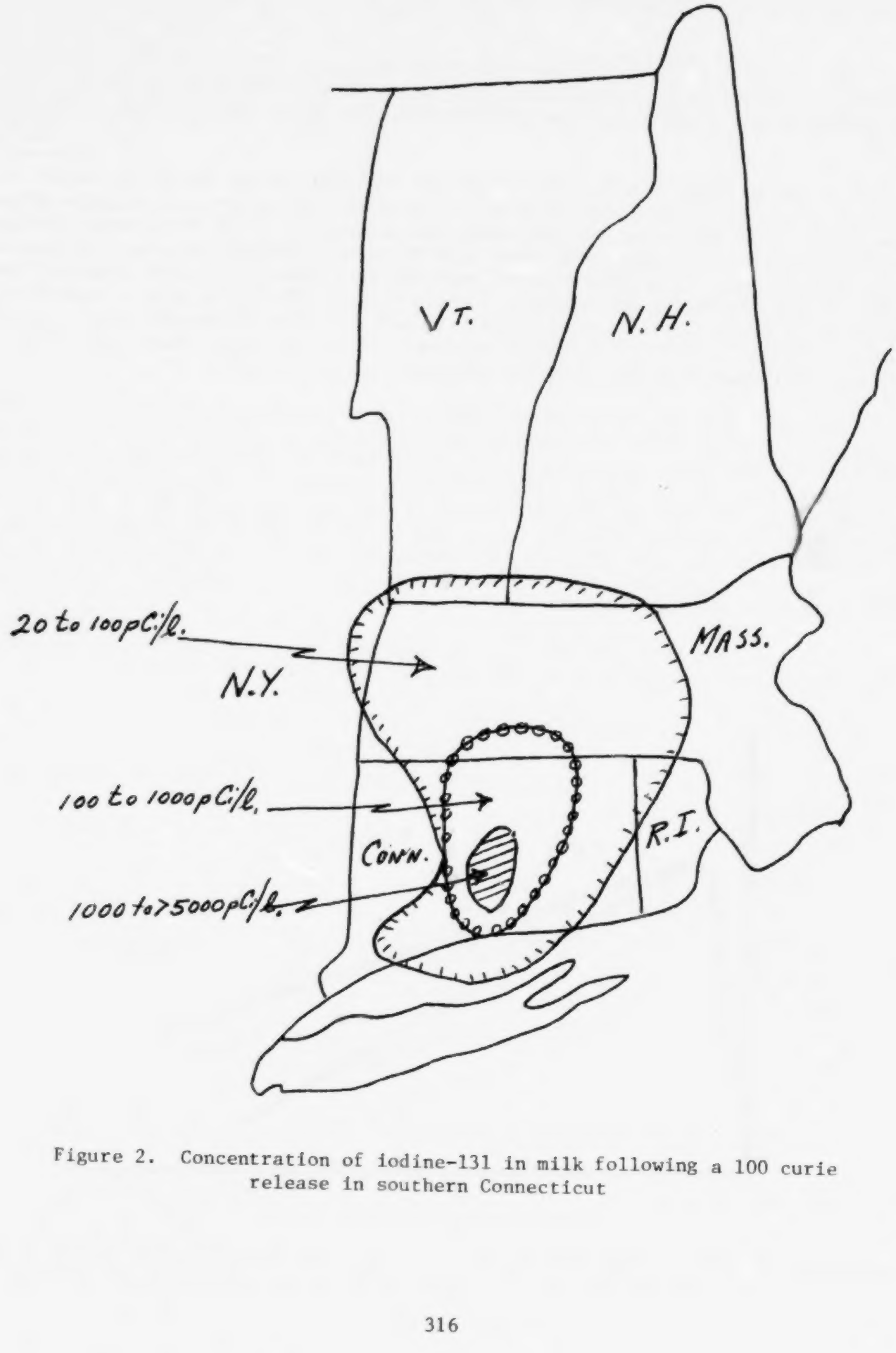


Figure 1. Typical curves showing radioactive decay of iodine-131 in milk after single deposition and protective action taken 24 and 48 hours post accident.



VT.
N.H.
MASS.
N.Y.
CONN.
R.I.
20 to 100pCi/l.
100 to 1000pCi/l.
1000 to 75000pCi/l.

Figure 2. Concentration of iodine-131 in milk following a 100 curie release in southern Connecticut

RESULTS OF THE EPA ENVIRONMENTAL RADIOFREQUENCY RADIATION MEASUREMENTS PROGRAM

F.L. Galpin, T.W. Athey, N.N. Hankin, and D.E. Janes
U.S. Environmental Protection Agency
(Presented by Floyd L. Galpin)

The Environmental Protection Agency has an active program to determine what controls, if any, are needed to protect public health and the environment from the undesired effects of environmental nonionizing radiation. The nonionizing radiation activities in EPA are divided between two offices. Biological effects research is conducted by the Health Effects Research Laboratory (Research Triangle Park, NC) in the Office of Research and Development. Environmental measurments, environmental evaluation, and the development of guidelines are carried out by the Office of Radiation Programs in the Office of Air and Waste Management.

Reorganization Plan No. 3 of 1970 transferred the function and authorities of the Federal Radiation Council to EPA. This function, as indicated in 42 U.S.C. Sec. 2021, directs that "The Administrator shall advise the President with respect to radiation matters, directly or indirectly affecting health including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." The goal of the EPA program is to determine the scope of the environmental nonionizing radiation problem through a measurement and research program and to recommend, if necessary, the controls required to protect the health and the environment including guidance to Federal agencies.

We are gathering data on population exposure and biological effects in order to reach a decision early in calendar 1978 on whether EPA should establish Federal guidance for environmental exposures to radiofrequency radiation standards. We will then discuss how a survey of environmental radiofrequency levels is planned and give some results of our measurements program.

Nonionizing Radiation Standards

Nonionizing radiation protection standards have exposure limits that differ widely among countries. The limits for the Soviet Union, Czechoslovakia, Poland, and the United States are summarized in simplified form in Table 1 (1).

The occupational exposure standards of the world generally fall into three groups on the basis of their exposure limits. In the most conservative group are the standards of the Soviet Union and Czechoslovakia with limits in the range of tens of microwatts per square centimeter. In the middle group are the standards of Poland, Sweden, the Bell Telephone Labs (U.S.), and the N.V. Philips Company of the Netherlands with limits in the range of hundreds of microwatts per square centimeter up to about one milliwatt per square centimeter. In the most permissive group are the standards of the U.S. and most of Western Europe.

In the United States the principal standard is that of the American National Standards Institute (ANSI) which was reaffirmed with minor changes in 1974 (2). The Department of Defense has had a similar standard since about 1953 (3). In 1971 the Occupational Safety and Health Administration (OSHA) adopted the ANSI standard as a national consensus standard (4) and it is now the legal standard for occupational exposure in the United States.

Standards for exposure of the general public are generally about a factor of ten more restrictive than the occupational standards. At the present there are no general public health or environmental standards in the United States, although the ANSI occupational standard is usually followed.

Certainly an environmental exposure standard should not exceed the occupational standard and perhaps should be lower. The occupational guide implies that the health conditions of the worker are known, that the actual exposure can be controlled, and the daily exposure is limited to approximately 8 hours. None of these conditions apply when dealing with the uncontrolled exposure of the public at large. This suggests that a general environmental limit of 10 milliwatts per square centimeter applied to large population groups may not be prudent. On the other hand, it is not clear at what point a lowered exposure would satisfactorily compensate for the uncontrolled aspects of general population exposure.

Careful examination is being given to the range between 1 and 10 milliwatts per square centimeter in an attempt to define an acceptable exposure level for large population groups under uncontrolled exposure conditions. The closest scrutiny is being given to the lower end of the range. This does not preclude the promulgation of even lower levels should later biological data indicate that standards should be set below the indicated range. Due consideration must be given to frequency range and duration of exposure. The strongest factors to be considered in choosing environmental exposure criteria are the protection afforded, the means of providing for control, and the economic impact on both the user of the source and the consumer of source related services.

Planning a Metropolitan Survey

The measurement program to determine environmental radiofrequency radiation exposure levels in urban areas requires detailed planning to ensure that the objectives of the program are accomplished. These objectives, very briefly stated, are: (1) describe urban area environmental radiation levels as completely as possible giving emphasis to areas containing the majority of the population and locations near the highest power transmitters, and (2) determine exposure levels that, because of unique locations of transmitters, may result in relatively high level exposure (compared to median exposure levels) to few persons.

Seven cities were selected for environmental radiation level measurements in the first, "eastern" phase of the program, September 1975 to October 1976. Boston, Atlanta, Miami, Philadelphia, New York, Chicago, and Washington, D.C. were selected primarily because they represent major population centers and, in some cases, different types of source distributions. It was determined that a measurement trip to a city, using EPA's instrumented van, could be scheduled to begin about every 2 months with 2 weeks of this time devoted to travel and measurement. For the last four cities visited, measurements were made at about 40 locations in each city over a 10-day measurement period.

The cities were surveyed in an order that optimized favorable weather during measurements; i.e., avoidance of snow, ice, and temperature extremes.

The planning elements involved in the preparation for each metropolitan survey are:

1. Source identification, specification, and location involving identification of the FM, TV, and AM transmitters in the area; determination of transmitter frequency, power, operating times, street address, height above ground, location (whether on supporting towers or building roof tops); description of nearby terrain or structures; grouping of transmitters on the basis of being co-located on one supporting structure;

2. location of all transmitters on street maps of the area, identification of areas of highest population on area maps;

3. selection of potential measurement sites on area maps (50 to 60 potential sites selected);

4. site selection visit to city involving visiting and photographing all areas of interest at each potential measurement site (including transmitter towers and nearby tall buildings), and potential parking areas for van (requires 2 to 3 days);

5. final selection of about 40 measurement sites from photographs and notes to cover highly populated areas, most significant transmitters, and any unique exposure situations;

6. telephone contact with all persons necessary to authorize parking for van (when needed), and to make measurements in tall buildings - followed up by letter formalizing the requested authorization or cooperation; and

7. preparation of detailed measurement schedule specifying measurement location, date, and time of day and provision of schedule to regional office.

One item of interest is the coordination of measurement program activities with EPA Regional Offices, State and local health departments, and any local government agencies (or private organization) that may be involved in authorizing parking at any measurement location or access to specific areas in buildings selected for measurement. EPA's Regional Radiation Office is informed of the planned dates for the measurements in an urban area within their Region at least 2 months prior to the measurements. The Regional office is requested to provide detailed street maps of the entire area, and assistance for the site selection survey, which includes arranging for a Government automobile and a staff member familar with the area to act as a guide. The regional office arranges for secure overnight parking of the van and any public relations activity that they desire. This includes issuing press releases and setting up press conferences. Publicity is coordinated with the Office of Radiation Programs. In some cities we have participated in a single press conference and in others there has been no press coverage at all. If press coverage is desired, we prefer that it be scheduled in advance so as not to complicate the scheduled measurement activity. The regional office also informs any State and local government health agencies of the planned measurement activity well in advance of measurements.

The gathering of information relative to sources, requests for authorizations to use public or private facilities for measurements, and coordination of these activities with local authorities are accomplished by direct personal contact between those organizations and the ORP staff member assigned responsibility for planning the field measurements program. Usually, a Police Department or Roads and Streets Department permit for the entire period will enable the van to park anywhere on public streets or roads where public parking is not permitted as long as it does not interfere with traffic flow or cause a potential hazard. The police in some cities placed barriers to exclude normal traffic flow or parking so that measurements could be made. Use of sites in public parks, at schools, airports, and so forth, is usually authorized by the appropriate government agency supervising those facilities.

The results of our measurement activities, and the ease with which we are able to operate within urban areas, demonstrates the success of our approach to planning this type of activity.

MEASUREMENTS

Our measurement system is housed in a 27-foot van, providing complete portability for all the equipment, antennas, and computer. Figure 1 is a photograph of the measurement van, and figure 2 shows the equipment inside the van.

At each monitoring site we select, we make measurements in several different frequency bands, including all the broadcast bands, where pilot studies have shown that most of the power can be found. In the early field studies we could monitor 1to 2 sites per day, and with the present system we can complete up to 4 sites per day, with the changing of antennas being the rate-limiting step. A new broad-band antenna system scheduled for completion this summer should significantly improve our data collection efficiency.

Table 1

NONIONIZING RADIATION STANDARDS (SIMPLIFIED)

Occupational Exposure ($\mu W/cm^2$)

	USSR	Czech.	Poland	USANSI
Above 300 MHz	10	25	200	10000
30 - 300 MHz	6	25	106	10000

Environmental Exposure ($\mu W/cm^2$)

	USSR	Czech.	Poland	U.S.
Above 300 MHz	1	2.5	10	(none)
30 - 300 MHz	1	.25	13	(none)

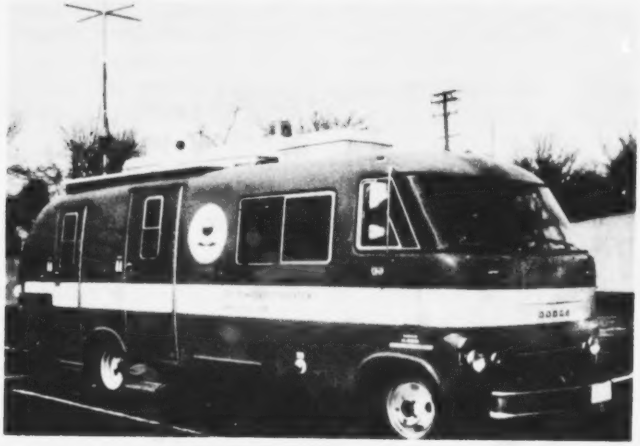


Figure 1. Environmental Protection Agency's electromagnetic radiation measurements van.

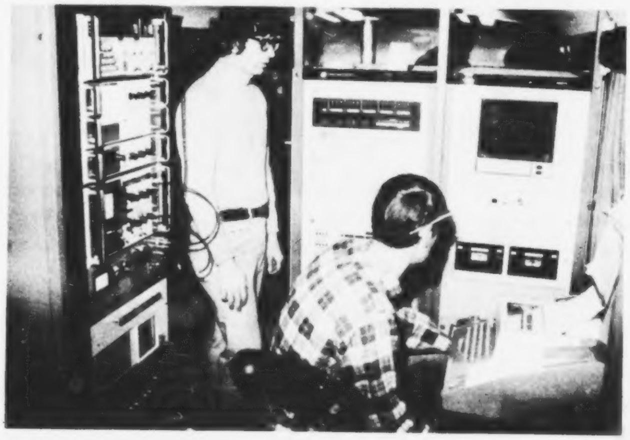


Figure 2. Measurement equipment and computer inside van.

Figure 3 illustrates the kind of data we are obtaining with the van. This particular example shows the average FM electric field intensity in units of decibels above a microvolt per meter (dBuV/m) for one of the measurement sites in Atlanta. As shown in the legend this is average data for 25 scans, digitized at 500 data points, taken at 10:30 a.m. on day 352 (December 18), 1975. The data were obtained with a 30 kHz band width and the site and the operator are identified. When the scans are complete the electric field intensities for the signals are converted to power density and integrated. For these data the integrated power density is 0.013 microwatts per square centimeter.

The data from the first four cities we surveyed were recently presented (5) and the data from all seven Eastern cities will be available soon (6). Figure 4 shows the distribution of power densities measured at 72 sites in Boston, Atlanta, Miami, and Philadelphia. In figure 4, "zero" on the horizontal scale corresponds to 1 microwatt per square centimeter, and -3 corresponds to 1 nanowatt per square centimeter. A number of tentative conclusions may be drawn based on an examination of this figure. The FM radio band contributes the most to environmental exposure between 50 and 900 MHz, followed by the VHF television bands. The land mobile bands make an almost negligible contribution to the total power density and other bands would make even smaller contributions. Note that only about 6 percent of the sites had power densities that exceed 1 microwatt per square centimeter.

Since the measurement sites were not distributed in the same way as the population, we cannot use figure 4 for population exposure information. However, we have developed a method for estimating population exposure from our measured data (7), and this method, when applied to the four cities, results in the population exposure curve shown in figure 5. We can see that the median exposure level for the population of these four cities is about 0.02 microwatts per square centimeter, while only 1 to 2 percent are exposed at levels above 1 microwatt per square centimeter. Preliminary results from three more cities suggest that the median population exposures for all seven Eastern cities will be about 0.01 to 0.02 microwatts per square centimeter.

Special Measurements

Because radiation patterns of transmitters are nonuniform, it is expected that levels would be greater at higher elevations. To look at the effect of height and antenna radiation patterns we have made a limited number of measurements in tall buildings in Chicago, Miami, and New York.

The building measurements were not done to locate areas where hazardous levels were thought to exist, but to allow us to study environments at locations closer to the main radiation beam of broadcast transmitters in order to supplement data collected near ground level. The measurements do verify that radiofrequency levels in tall buildings can be higher than levels commonly encountered at ground level, at least on the side of the building facing the source. The range of values for this limited study was 1.2 to 97 microwatts per square centimeter inside the buildings. A maximum of 228 microwatts per square centimeter was measured on the roof on one building.

The building measurements data have not yet been published, but they were presented to the Office of Telecommunications Policy's Electromagnetic Radiation Management Advisory Council during a public meeting last February. The February 21 issue of Science Trends (8) contained an article on the ERMAC meeting with the following opening line: "Radiation levels up to eight times higher than reported at the American Embassy in Moscow have been measured by government researchers in office buildings in American cities." This was picked up by the wire services and even the Russian newspaper, Tass. You will recall that in the Spring of 1976 there was a good deal of press interest in the intentional irradiation of the U.S. Embassy in Moscow with microwaves. The maximum intensity was reported to be 18 microwatts per square centimeter (9). Though there has been a good deal of speculation and conjecture in the press, there have been no health effects linked to the microwave exposure at the Embassy.

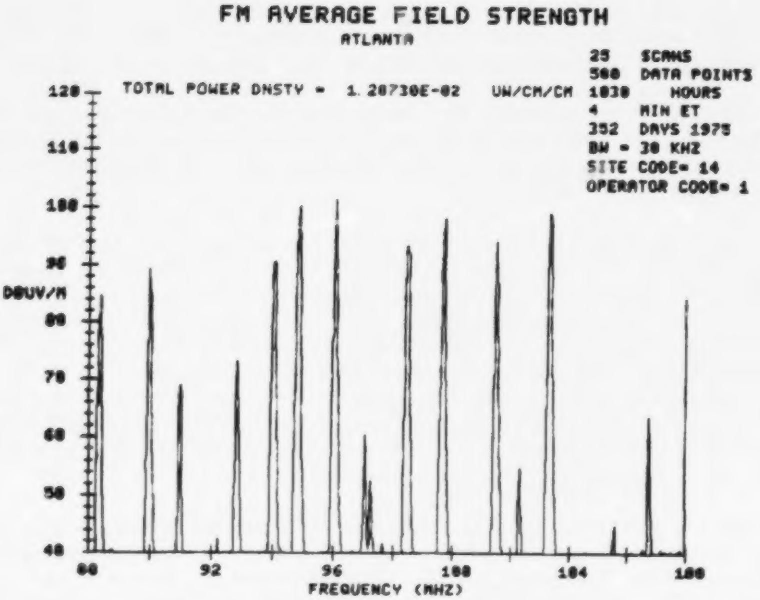
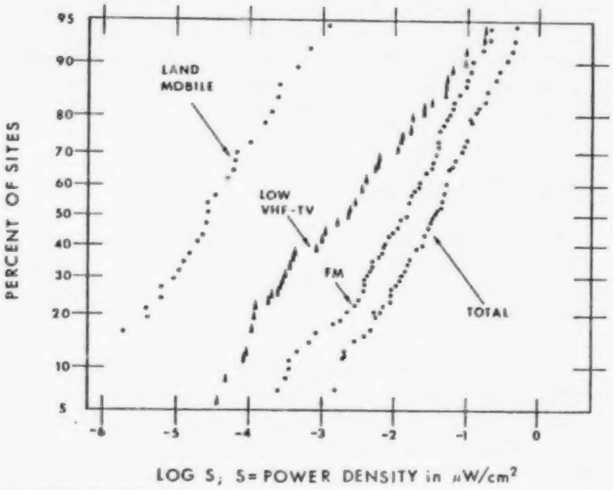


Figure 1

Figure 2



FRACTION OF POPULATION EXPOSED AS A FUNCTION OF POWER DENSITY

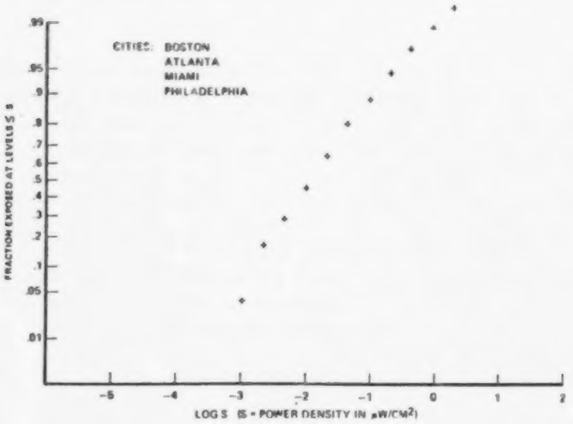


Figure 3

This was confirmed by a recent meeting that we had with the State Department on the matter.

There is a continuing press interest in the microwave exposure area and our building measurements in particular. We have given background information to several reporters and NBC news has spent a full day filming our nonionizing radiation research facilities and interviewing some of the EPA research staff. On April 28 we were asked by our Regional Office in Atlanta to call the building manager of 2 Biscayne Boulevard, the building where we made measurements in Miami. The manager indicated that NBC news wanted to interview people on the 38th floor about how they felt working in nonionizing radiation levels 5 times higher than those reported for the U.S. Embassy in Moscow. The 38th floor has not been developed yet and no interviews were made. We then called Regions II and V to inform them they might be receiving inquiries about the building measurements in New York and Chicago, respectively.

On April 29, we were contacted by a member of Sears management who related that NBC had called and asked to make measurements and to videotape scenes of the broadcast towers from the room on the 50th floor where EPA had measured radiofrequency levels. NBC also wanted to interview the occupants of the room, asking the same question given above. Sears' management decided against the interview but gave permission for the videotaping. When the NBC camera crew arrived the venetian blinds in the room were down, but open. They set up their solid state video camera and checked it and the scene. After determining that everything was fine, they raised the venetian blinds. The solid state camera then failed to operate, presumably because of radiofrequency interference from the increased levels in the room that were previously shielded by the blinds. NBC returned later with a film camera to get the pictures they wanted.

Another example of radiofrequency interference comes from some measurements made at the request of the staff of the Washington D.C. Hospital. The measurements showed that FM power densities on the order of 1 microwatt per square centimeter could interfere with the operation of a certain type of digital electronic thermometer used in a local hospital. This interference problem was cured by a change in thermometer design and replacement of the susceptible thermometers by the manufacturer.

SUMMARY

In summary, we feel that we can adequately characterize the nonionizing radiation exposures of about 98 percent of the population, and that the levels for this group could meet any exposure standard in the world. In some locations, such as tall buildings near broadcast transmitters, the levels may be hundreds of times higher than at ground level, but still probably always below the OSHA/ANSI occupational standard. Further studies are necessary to adequately describe the "above-ground" exposures to broadcast radiation in urban areas or in the near vicinity of other specialized sources.

REFERENCES

1. Czerski, P. Microwave and Radiofrequency Radiation Protection Standards, in Overviews on Nonionizing Radiation. International Radiation Protection Association, 1977.

2. American National Standards Institute. Safety Level of Electromagnetic Radiation with Respect to Personnel, ANSI C95.1-1974, Institute of Electrical Engineers, New York, 1974.

3. U.S. Army. Control of Hazards to Health from Microwave Radiation U.S. Army Technical Bulletin TB MED 270 (Air Force Manual AFM 161-7), 1965.

4. Department of Labor. Occupational Safety and Health Standards, National Consensus Standards and Established Federal Standards. Federal Register, 36 (No. 105), 10522, 1971.

5. Janes, D.E., R.A. Tell, T.W. Athey, and N.N. Hankin. Radiofrequency Radiation Levels in Urban Areas, in Special Supplement in biology of Radio Science, U.S. National Committee of International Union of Radio Science, Washington, 1977 (in press).

6. Athey, T.W., R.A. Tell, N.N. Hankin, D.L. Lambdin, E.D. Mantiply, and D.E. Janes. Nonionizing Radiation Levels and Population Exposure in Urban Areas of the Eastern United States. U.S. Environmental Protection Agency Technical Report, 1977 (to be published).

7. Janes, D.E., R.A. Tell, T.W. Athey, and N.N. Hankin. Nonionizing Radiation Exposure in Urban Areas of the United States, in Proceedings of the IVth International Congress of the International Radiation Protection Association, editor, G. Bresson, Vol. 2, pp 329-332, April 1977.

8. Kranish, Art. "Broadcast Radiation Levels," Science Trends, 37 (No. 19), p. 1, February 21, 1977.

9. Associated Press. "Screens Found to Block Rays at Moscow Embassy," The Washington Post, April 26, 1977.

LASER LIGHT SHOWS - A NEW CHALLENGE

Henry P. Copeland
Georgia Department of Human Resources

It appears in this ever-changing, quick-paced, try-anything-once society that nothing new would have any shock value. Maybe so. Society has apparently accepted a loud and sometimes regulated noise (commonly referred to as "rock music") and we of the older generation now worry that our teenagers will lose their hearing at rock music concerts.

However, because of our modern technology, the problems associated with these concerts have been compounded. Demonstration lasers have made their debut. These devices bring light to excite the senses, to dazzle the eye, and to possibly cause biological damage.

Let me begin by asking what is the nature of ill effects that can be suffered as a result of exposure to light from these high-powered lasers?

Though it is true that the most powerful lasers can cause skin and tissue damage, the biological significance of laser light ultimately deals with ocular damage--primarily to the retina. As stated in the Occupational Safety and Health Administration's Notice of Proposed Rule Making for Exposure to Laser Radiation, the World Health Orginization's report on medical surveillance concluded that "it is unlikely that a near threshold retinal lesion will be identified as such by ophthalmoscopic examination, even if carried out by an experienced opthalmologist." Furthermore, "in most cases it would be impossible to differentiate between laser induced and other retinal lesions and pathologies after about one week from exposure (and) if retinal change is identified, no therapy can be offered." (1)

Visible and near infrared range laser radiation sources present a unique situation with respect to the eye, as the energy density (or exposure) incident on the eye tends to be focused to nearly a point on the retina, thereby concentrating and greatly increasing the energy density at the retina. The results of excessive exposure may thus be a pinpoint burn on the eye that may result in a blind spot or loss of visual acuity in that immediate area. If such a laser beam were scanned across the eye, the result might be a streak of damage on the retina. But the chances are that such damage might not be readily apparent to an individual immediately after exposure. Even at a later date, gradual loss of visual acuity because of this exposure might not be associated with the exposure.

Our first introduction to lasers used for entertainment purposes came several years ago and in a somewhat less complicated form then than presented at rock music concerts.

During the summer of 1972 our office became aware of an entertainment game using lasers, in which a craft emitting a red ray, could, if aimed correctly, shoot down an alien craft. This game was the first known entertainment use of lasers in the States.

The potential hazards involved in the use of the game were immediately recognized. In the laser game the beam stop was a glass viewing window which was painted flat black in the area where the beam was to strike. With ageing the paint began to crack and peel and permitted the laser beam to pass into the environs at the eye level of the smaller patrons. At that time our office had no idea of the power of the HeNe Laser nor did we know the divergence of the beam, either by documentation or by measurement. There was no instrumentation available to us.

The game was a moderate financial success for its owner and other games were planned using lasers. However, for unknown reasons, which may have included a requirement that laser devices in Georgia must be registered with the Department of Human Resources, possibly some surveillance, and a request for a safety analysis of the setup, the use of the device was deterred.

With the passing of the laser game, the Department proceeded with the necessary, more routine work in ionizing radiation. But fate would not allow us the complacency of a problem solved. Over the horizon were ominous bright clouds. Beginning in 1975, laser light shows were destined to sweep across Georgia. With glowing laser beams burning through the air, Atlanta was to be beseiged. Buildings, it was said by one group of laser users, would be set ablaze with laser light. Laser users proposed to paint the skyline. In a short period of time thin streaks of colored light whipped and zig-zagged across buildings, not exactly setting Atlanta ablaze, but they did bring the realization that laser light shows could create a situation where a public health consideration was paramount.

Before the performance of the first laser light exhibition in the State, it was realized that a safety analysis of the planned use of the laser system should be made. Atlanta was to be painted with light. What of the people in the buildings? Where else would the beam be directed? The answers to these questions were astounding. The laser promoter planned to direct a beam on a helicopter above the crowd and to scan a small fountain at the base of a building next to a multitude of people. Little thought was initially being devoted to the nature of the surfaces to be struck by the beam. Where these surfaces specular, diffuse, or transparent, and to what extent?

The new challenge was apparent and our group accepted it. We had a new responsibility--that of laser radiation safety. Armed with our registration requirement, we talked to the members of the laser light company and requested a safety analysis. The request was honored, but not fully. Investigation of the setup and projected plans of the show were warranted. Building managers were telephoned. City officials were contacted. Our own analysis was made. Recommendations for use were given to the promoter. The show did not go as planned the first night because of a lack of sufficient water pressure to cool the lasers. When that problem was solved, the show proceeded on the two following nights with the lasers operating at a reduced power level at our request. Mr. Clifford Blackman of our staff developed a computer program in a very brief period of time whereby we were able to calculate safe power levels and safe distance as based on ACGIH standards (2).

Several months after that first outdoor show, we learned that a well-known artist would set up a permanent laser display, or "sculpture," in one of the large buildings in Atlanta. This sculpture was to be a fixed display and would use an 18-watt Argon laser. Initially, the beams were to be aimed at the angled indoor wall of a hotel in the complex and would be reflected in a more or less specular manner depending upon the exact wall surfaces to be struck. Our first survey of the display indicated that, because of the lack of cleaning of the optical beam splitters and mirrors in the beam path and because of the small beam outlet ports in the enclosure surrounding the laser, numerous diffraction rings and extraneous beam spots were being created that sent unwanted light in directions that were accessible to people. At that time, our office requested and received aid from the Bureau of Radiological Health, FDA, in an effort to determine whether or not a public health hazard existed with regard to this laser display. Our office did not have sufficient instrumentation with which to measure the power levels of these beams.

After the initial hotel survey, the beam configuration was changed so that multiple reflections were produced by mirrors located at various points within the building. More on this subject later.

The year 1976 marked the advent of the use of high powered lasers in rock concerts in Atlanta. One to four lasers, ranging in power from 5 to 15 watts, are generally used in these shows. These performances are "one-night stands" where the groups come into town one day and are gone the next. Since the lasers are usually set up from 1 to 5 hours prior to the concert, there is considerable time pressure on our staff to perform whatever checks we can during that time.

The first of these rock concerts that our staff monitored was an outdoor event, which was to start at 3:00 p.m. and last until midnight. The rock group using the lasers in company with the music were the main attraction and were next to the last to go on. We required the laser operator to register the lasers and requested a laser safety analysis. Our office considered the analysis we received to be less than adequate, so we then discussed the proposed use of the lasers with the operator. We were informed that (1) the lasers would be operated in the scan mode, that (2) there was only 1 chance in 10,000 of scan mode failure, that (3) beam limiters would be employed to keep the beam from scanning the 50,000 spectators present, that (4) in the unlikely event of scan mode failure the beams would be turned off by fail-safe devices, that (5) the divergence of the beam would be 5 milliradians, and finally (6) that lasers would be operated at a reduced power level during the performance. We felt that if all these measures were taken, then the light show could be presented in a relatively safe manner. The lasers were set up at 8:00 p.m.; i.e., during the actual performance of the concert.

I must ask you at this point to visualize the scene during the performance. Here we had an eager, excited crowd of 50,000 young people who had waited for 8 hours for the star performers, a crowd whose pupils were dilated since it was near midnight, a crowd who came to see a laser light show and who would get one!

A most remarkable fact resulted from this show. Only one of the promises made by the laser operator was kept. Indeed, the lasers did operate in the scan mode--except on three occasions when the beam was directed to the audience. There were no beam limiters, scan failure did occur three times, the beam did not turn off, the beams were directed into the crowd, the beam divergence appeared to be much smaller than stated, and, the power levels did not appear to have been reduced.

When all of these things were observed by our staff it was already too late to take any truly effective action. We learned that more strict requirements would have to be imposed prior to these shows, if restrictions were to do any good in the future.

For visible-range laser control, one must deal with a highly directional source that may have an extensive hazard range. The laser source may be concentrated by optical instruments such as binoculars. It may be almost as hazardous when reflected and specular, it may be treated very casually by untrained persons since it is "only light." Exposure limits for this type of source may by difficult to determine when the laser is used in the "scan" mode. Obtaining adequate instrumentation for evaluation, having the necessary expertise to use the instruments and to interpret the results, translating results into realistic recommendations based on safety standards or regulations, and backing up these recommendations with the force of law may all be difficult problems to solve.

Since that memorable performance, we have observed a total of nine additional ones and we have noted the following:

(1) Many of the stage personnel treat laser beams rather casually during setup. We have one eye witness report that a stagehand was lighting cigarettes from a laser beam (3).

(2) The audience is often deliberately exposed (or treated) to scanned intra-beam or specular beam viewing conditions.

(3) Some members of the audience literally try to "bathe" in the laser light. In fact, the laser operator seems to represent some sort of a mystical priest and his followers are referred to as "laser groupies."

(4) Not all of the laser operators seem to be aware of laser safety. Each of the operators seem to feel that they are operating safely, but several have been quoted as saying, in essence, that "We're o.k., but we don't know about the other guys."

(5) On four occasions during the nine performances scan failure did occur. Two of these occurred while the laser beams were directed toward the audience.

For most of these light shows our office has been able to borrow instrumentation from the Georgia Institute of Technology, pending the acquisition of our own equipment, and we have attempted to measure power levels, beam divergence, scan parameters, and so forth. However, we have had only partial success in this effort because of certain difficulties that we have encountered.

The environmental conditions for evaluation at rock concerts are usually far from ideal. One usually has various other activities going on around the stage, including testing of other lighting effects, sound equipment, and so forth, which may cause difficulties. Time is usually at a premium, with pressure on the evaluator to get through so that the stage crew can finish their setup. The evaluator must constantly be aware of changing ambient light conditions and he may need to make adjustments accordingly. Making measurements at a distance can be difficult. Stage vibration causes problems in keeping the detector centered in the field. An understatement could easily be made that we have found that monitoring during a performance is extremely difficult.

Some of the types of equipment available to us that we have found useful thus far include a relatively fast response power measurement meter with an attenuator and detector, a 100 MHZ bandwidth oscilloscope to aid in assessment of pulsed or scanned beam conditions, a pair of 7 x 35 (average size) binoculars to check binocular viewing if applicable, an adjustable iris to aid in measuring the diameter of the beam, an adjustable tripod with an assortment of holding devices to attach equipment, and a set of laser safety goggles to be worn when working in the immediate area of the beam, and so forth.

There is one important fact that we have learned concerning the use of power level meters. We have noted that if measurements are made without an attenuator in the beam, the detector may be "swamped" and can produce readings that are too low. It may thus appear that the power level is safe when, in fact, it may not be. The frequency response of the power level meter must also be considered for "scan" mode laser measurements. Regardless of the difficulty of doing these measurements, we have seen improvements on the part of the laser operators in the area of safety. These measurements, for that reason, are worthwhile.

Up to this point I have been discussing the problems and possible hazards associated with laser light shows. I believe it is time now to discuss some possible solutions to these problems, and these may be divided into short-term basis, we would recommend that reciprocal notification between States be established so that each State may receive notice of impending light shows. Secondly, measurements can be made and safety analyses can be required for each light show. We have noted that increased surveillance has had a beneficial effect on the safety of these shows.

On a long-term basis, we feel that those States that do not presently have enabling legislation for the control of nonionizing radiation should consider obtaining such legislation. We feel that those States that do have this control should write stringent and comprehensive regulations, using Federal guidelines where available, for the use of laser devices in the State. We have written these and will begin the adoption process this year. Finally, we recommend that the Bureau of Radiological Health, FDA, consider that these laser operators be subject to the performance standard for lasers and that they not be allowed to operate lasers that are higher in power level than class II. The Bureau did determine that the laser sculpture was subject to the standard and that the artist would have to change his installation so it would be in compliance with the performance standard. This the artist has agreed to do.

Inasmuch as large numbers of people are being exposed to potentially hazardous light levels from laser light shows, it is necessary for the sake of public health that we meet this new challenge.

REFERENCES

1. World Health Organization - Working Group on Health Effects From Lasers - October 1974.
2. Blackman et al; August, 1976 Health Physics, Vol. 31, No. 2.
3. Private Communication - 1976

CONTROL OF LASERS IN THE ENTERTAINMENT FIELD

Francis J. Bradley
New York State Department of Labor

When I submitted this title, I did not realize that someone else would be discussing the same topic, and some of my comments are fairly similar, except we have one advantage in that we do have a fairly complete and comprehensive laser performance standard in the State.

The use of lasers for their artistic potential has been exploited for the last 7 to 8 years. In the late 1960's, I can recall individual artists who gave exhibits using the laser to set up color patterns for their artistic effect. Holography is being exploited for similar reasons and there exist schools of holography in New York and in San Francisco and probably other locations around the country where this technique is being taught. These older art forms are child's play compared to what is being suggested and attempted in the last 3 years.

I am going to describe how lasers are used in this application, and finally I will mention a document that is being developed with the cooperation of the BRH; a Suggested State Regulation for the Use and Control of Lasers, which will include an Appendix B with Guidelines for Control of Lasers at Light Shows.

We can roughly divide the use of lasers at these shows into (1) low-power devices; that is, lasers where the total power output is less than 1 watt, and where the hazard is strictly to the eye, and these particular lasers are usually helium-neon and a few krypton lasers); and (2) shows using high-powered lasers which are argon and krypton lasers, wherein the power levels may extend up to 30 watts, and the hazard may include skin burns as well as eye injuries.

For indoor shows, at the present time, it is usually adequate to use lasers with power levels of less than 10 watts, but at outdoor shows they require (or at least higher powers are contemplated) power levels as high as 30 watts. I go that high since one firm stated it used a 27-watt laser in Florida.

I will describe three firms using low-powered lasers, and then four firms using high-powered lasers. Firm A uses helium-neon lasers, in a school for instructional purposes in the making and projection of holograms. Such holograms have found application in advertising and artistic photography besides the technical applications that you may be aware of.

The six lasers in use at this particular school have power densities that range from a 0.1 to 1 watt per square centimeter, and the total power output in the raw beam ranges from about 0.5 to 10 milliwatts, maximum (see table 1). We have had no difficulty with this application except for one stolen laser.

Firm B uses five helium-neon lasers with raw output power densities that range from a 0.1 to 0.8 watt per square centimeter. The firm also uses a helium-cadmium laser with maximum power density of 0.3 watt per square centimeter. This laser emits in the deep blue and uses an ultraviolet filter to block out all lines below 400 nanometers, which contribute nothing to the show. I do not want to intimate to any of these people that they can put up a fluorescent surface and they can see the invisible beam, since we have enough problems with the visible beam.

The firm projects the beam over the orchestra onto the back wall of the ballroom in this particular application. They followed our guidelines for these light shows, first, by using a certified operator, which is a requirement of the New York State Code for Mobile Lasers and, secondly, lining up the beam on the back wall before the arrival of the customers.

Table 1. Characteristics of lasers in use in entertainment field

Firm	Type of laser	Number of lasers	Frequency (nm)	Power (watts)	Power Density (W/cm^2)	Number of workers potentially exposed
A	HeNe	6	632.8	0.005-0.009	0.1-1.0	8
B	HeNe	5	632.8	0.001-0.01	0.1-0.8	2
	HeCd	1	450	0.01	0.3	
C	Kr	1	476.2-647.1	1 (all lines)	56.5	2
D	Ar	3	454.5-514.5	4	350	4
	Kr	1	476.2-647.1	0.75	--	
E	Ar	1	454.5-514.5	4	230	4
	Kr	1	468-676	6	300	
F	Ar	2	454.5-514.5	8	450	5
	Kr	1	476.2-647.1	5.5	310	
G	Ar	1	454.5-514.5	20	1130	2
	Ar	1	454.5-514.5	4	230	1
	Ar	1	454.5-514.5	1	60	1

This requirement is important because every setup is different, and it takes time and a great deal of hit and miss before one gets the beam to go where you want it to go.

One must remember that most laser light shows that we have seen to date are one-night stands, where the equipment is brought in and set up on the day of the show and then dismanteled after the show. Therefore, a great deal depends upon the competency and the conscientiousness of the laser operator. This repeats exactly what Mr. Copeland said in the previous paper. Also, in this application, Firm B is the only one to use a helium-cadmium laser to date.

The final firm, Firm C, with the low-power lasers uses a 1-watt krypton laser. For some of these light shows the krypton laser is more versatile with emissions in the blue, green, yellow, and red, with total power output for all lines of about 1 watt. The emission for the red line is 0.1 watt. This firm utilizes a rear projection screen of about 20 x 30 feet with a 50 percent reduction of the light intensity in passing through the screen.

The audience, therefore, views the laser light pattern which is synchronized to the music, and is mostly incoherent light after it is passed through the screen. The optics at the laser head, besides splitting the beam into the four colors, also diffuses, reflects, and refracts the beam to give rise to different geometric and other amorphous colored patterns.

The visual effect is an integral part of the show in this particular application, and the laser operator is considered part artist.

The next group of firms provide lighting effects using high-powered lasers. They are always argon and/or krypton with total power normally exceeding 1 watt, and power densities that range from 100 to, in a recent application, over 1,000 watts per square centimeter in the raw beam and before optical components. Besides potential for retinal burns, there is always present the possibility of skin burns in the case of a stationary beam or up close to the scanning beam. These high-powered lasers can produce startling lighting effects, and besides music music at the rock concert, the object is to startle the audience; smoke bombs go off, firecrackers explode, and, now, these high-powered lasers have been added to the retinue of tricks of the rock groups.

This is where you may start to experience problems, since the audience wants to be visually blasted, and some firms are only too willing to accomodate them.

To handle these high-powered lasers requires expertise or persons can get injured; first of all, the persons on the stage in or near the laser and near the optical train, and, secondly, if the beam is not properly controlled the audience may be exposed to excessive levels of laser light; the effects of which we do not know all the potential for injury as yet. Finally, these high-powered lasers are starting to appear in nightclubs and discotheques. To date, we have none operational in New York but they have been proposed and are operating in other States.

I am going to summarize the operation of four firms who provide laser light service to travelling rock groups or put on light shows. Firm D uses three argon lasers, 4 watts; each, and one krypton of about 0.75 watt. Power density in the argon beam is about 350 watts per square centimeter.

The first lighting effect utilizes two crossed argon beams forming various geometrical patterns on the roof of auditoriums or overhead screens for outdoor shows. Some of these patterns are familiar to electrical engineers, because they are Lissajous patterns, the same as you would see on a cathode ray oscilloscope. The Lissajous patterns are made in the similar fashion, except you work on a laser beam with the x-y scanners; usually mirrors. This effect lasts approximately 12.5 minutes.

The second effect includes enclosing one singer in a pyramid of green argon light coming from a laser suspended over the performer, and during the song the krypton laser projects the four lines through the pyramid out over the audience; the total effect lasting approximately 15 minutes.

Light is only visible if it is scattered off the particles in air if you are out of the direct beam. Somewhat surprisingly, even in New York, the air can be clean up to the point where such beams are next to invisible in a large auditorium. This leads to the use of some type of smoke or CO_2 generator, and in some cases, small strips of foil.

Initially our requirements forbade the use of any type of particle or foil artificially generated, but we have had to relent, because of the obvious need to see the beam, but we do not permit foils because of the greater probability of specular reflections off the foils into the audience.

With the EG & G power meter, the maximum readings we have obtained off the green pyramid was 0.1 microwatt per square centimeter. This is with the smoke blowing into the pyramid.

Firm E uses two high-powered lasers; a 4-watt argon laser with 230 watts per square centimeter, and a 6-watt krypton capable of 300 watts per square centimeter, with all lines out.

The firm produced a total of four lighting effects with one laser mounted onstage behind the performers, and the other laser mounted in a truss above the performers. Again, with mirrors and mechanical choppers, various multi-colored patterns, and one effect enclosing the performer in a cone of green light--the performer in the cone or pyramid of light is the latest gimmick. Each effect lasts between 20 and 40 seconds with a smoke generator onstage to make the patterns visible.

Firm F uses three high-powered lasers, two 8-watt argon lasers with outputs of about 450 watts per square meter, and a 5.5 watt krypton laser with output power density of 310 watts per square centimeter. The three lasers are mounted in front and below the stage level, a total of nine effects are generated by these three lasers; in some cases a moving pattern, and in other cases, a laser light sculpture generated by bouncing the laser beam off various mirrors mounted in the auditorium.

Each laser light effect lasted from 20 to 120 seconds. During most of 1976, the intent of these firms was to startle and tease the audience with the laser; therefore, the laser was on only for seconds at a time. But in the last few shows, the laser was on during the complete song or musical piece, lasting approximately 15 minutes, and the laser was used either in place of or as an adjunct to stage lighting.

The final firm, Firm G, proposed to use lasers for an outdoor light show using a 20-watt argon laser with output power density of 1,130 watts per square centimeter, and a 4-watt argon with 230 watts per square centimeter, and a 1-watt argon laser with 60 watts per square centimeter. The 20-watt argon was to project a beam into the air to produce six effects that were to last a total of 3 hours, and the two lower-powered argon lasers were to be used to produce a laser light sculpture pattern by the use of mirrors.

Now, how do we control such uses? In 1972, Code Rule 50 was promulgated to cover the industrial and commercial use of lasers in New York State. Fortunately, this particular Code was a performance type of regulation, because at that time, and certainly in the prior 3 or 4 years in its formative stage, the use to which the high-powered lasers are put in the entertainment field was not anticipated.

The Code Rule has the following provisions, which are applied to these firms to control their use in the entertainment field and permits them to obtain the visual effect without, it is hoped, any injuries now or in the future:

(1) The firm providing the laser light services must register and provide a sketch showing beam path, velocity of scan beam, and give the power density in all occupied areas. If the laser beam is going to be used outdoors and pointed into the air, prior FAA approval is required.

(One firm stated that they used lasers at the Washington Monument on July 4, 1976, and that they received letters from persons who were as far away as 100 miles and saw the beam. So, the need for some type of air space control is obvious.)

Because of the information reported by Dr. William Ham (1) regarding the increased sensitivity of the eye in the blue-green spectral region, until recently we have restricted the plane of coherent laser beam across the audience in the 400 to 600 nanometer region.

One firm, to test this requirement, conducted a controlled experiment on a captive audience, and played the argon beam off a mirror ball, a commonly used device at shows and discotheques, and everyone got sick but immediately recovered. This convinced him of the need for caution in the spectral region.

This brings up an interesting topic; I have been asked by firms who are providing this type of service if I know anything about psycho-optics. I have been told that certain scan frequencies similar to the frequency of brain wave patterns should be avoided. In the past, I have heard of persons using lasers in the construction field who would be inadvertently exposed to the scan beam and would sometimes experience afterimages in the evening. Whether these are related phenomena or not, I do not know.

Originally, we forbade the scanning of the laser beam into the audience in the spectral region from 400 to 600 nanometers, and this made our job a little easier. (Appendix B, SSRL does permit scanning the audience, but within strict limits.) To return to Code Rule 50 provisions,

(2) The operator of the mobile laser must be certified.

This means he must have at least 1 year's experience or take a laser training course, and pass the State certification exam. This, we feel, is the single most important provision of the code rule in this particular type of application. Since no matter how well the equipment is built and protected, which is not the case now, no matter how much surveillance we provide, in the final analysis, the only assurance we have that the equipment will be operated safely is if the person is appropriately trained and qualified. There is attached to this paper the present version of Appendix B, Suggested State Regulations for Lasers.

REFERENCE

(1) Ham, W.O., Jr, H.A. Mueller, and A.N. Clarke. "Retinal Sensitivity to Damage from Short Wavelength Light." Proceedings of Symposium on Biological Effects and Measurement of Light Sources (FDA 77-8002), pp. 37-42 (1976).

APPENDIX B*

GUIDELINES FOR LASER LIGHT SHOWS

(*Part of Proposed Suggested State Regulations - Lasers. Task Force Members: J. Rogers, formerly with Los Angeles County Health Department; J. Thiel, Texas; F. Bradley, New York; and C. Froom, BRH/FDA.)

(1) Each laser facility and mobile laser shall be registered in accordance with the provisions of this SSRL.

(2) The laser operator shall demonstrate his competency to operate laser safely by having taken and passed an acceptable laser training course such as given at several universities or sponsored by technical organizations.

(3) Before a laser show is permitted to open (either at a permanent or temporary site) the show's laser safety officer (LSO) shall provide the Head of the Agency responsible for implementing the SSRL with a sketch showing the beam path, velocity of scanned beam in occupied areas or where beam strikes the wall or other structure. In case of open air shows where the laser is projected into the sky the LSO shall provide the spot power and energy densities at 0.5 and 1 mile from laser and contact Federal Aviation Administration for air space approval. Include in report an analysis to show that laser beam exposure levels in occupied areas and where beam strikes the wall or other structure are as follows:

Less than or equal to 1 microwatt per cm^2, CW mode and
less than or equal to 1 microjoule per cmk^2, pulse mode,
in spectral range from 400 to 700 nanometers.

(4) The laser shall meet the following specifications:
   (a) Total maximum laser power output for all laser lines and before optics shall be less than 5 watts.
   (b) The spectral laser emission shall be in the range from 400 to 700 nanometers only.
   (c) A conveniently accessible point near the output of the laser shall be available to insert a power meter to check the laser power level or such power measurement capability shall be built into equipment for direct read-out.

(5) The following precautions shall be taken during alignment procedures:
   (a) Alignment of laser optics,
      (i) This will be done only by a qualified individual with beam power turned down as far as practicable,
      (ii) The public shall not be present,
      (iii) Protective goggles shall be worn where necessary.
   (b) Alignment of scanning laser beam patterns:
      (i) This will be done by person approved in Item (2).
      (ii) The laser shall be in scanning mode,
      (iii) In spectral range from 400 to 700 nanometers the maximum permissible exposure levels of the scanning laser beam shall be as follows:
      less than or equal to 1 microwatt per cm^2, CW mode and
      less than or equal to 1 microjoule per cm^2, pulse mode
      in all occupied areas and where the beam strikes the wall or other structure.
      (iv) No laser radiation outside spectral range between 400 to 700 nanometers shall be emitted.

(6) The laser system shall be rigidly fixed on a secure mounting.

(7) Unless the scanning laser beam has two independent interlocks which shall turn the beam off or deflect beam away from exit aperture, in case the beam stops scanning, the laser beam must be terminated by the fire retardant material.

(8) On-stage an area on both sides of laser beam path shall be designated a high radiation area and barriers shall limit access to this area while laser is operating.

(9) The laser control console shall be sited in a position such that the acting area, beam path and laser display can be viewed by operator.

(10) In cases where "mirror balls" are used the maximum permissible exposure levels as given in (5) (b) (iii) for the spectral range from 400 - 700 nanometers shall be measured or calculated while mirror ball is in stationary mode.

(11) No specularly scattering foils or metallic strips shall be injected into laser beam during laser light show.

(12) The laser shall be capped or effectively enclosed while not in use.

(13) Before each laser show the output laser beam power shall be checked and recorded and all safety interlocks shall be checked.

(14) The laser shall be equipped with a key operated "ON-OFF" switch and when the authorized operator leaves the laser area he shall turn off the laser and remove key.

(15) All safety interlocks shall be of the type that will not automatically restart laser when fault is removed.

(16) All electrical wiring and connections shall meet requirements of National Electrical Code and local fire codes.

LASER STANDARD AND RELATED BRH COMPLIANCE EXPERIENCE

Robert G. Britain
Bureau of Radiological Health, FDA

The performance standard for laser products has been in effect for over 10 months, having become effective on August 2, 1976. In that time 119 manufacturers have submitted 437 reports to BRH covering approximately 600 models of lasers, laser systems, and products incorporating lasers. These reports are required to be submitted to demonstrate that the products comply with all aspects of the standard, and that a testing program is being conducted by the manufacturer to assure continued compliance, and that the records are maintained documenting these tests and identifying all customers using these products.

In the past 18 months, we have held meetings at the Bureau with over 85 manufacturers or potential manufacturers. Since the standard took effect, 47 manufacturers' plants have been inspected and we anticipate by the end of the fiscal year that approximately 85 will have been inspected. All currently reporting manufacturers will have been inspected by January 1978. The number of manufacturers reporting certified products increases by an average of 5 per month, and an additional 20 potential manufacturers per month are identified. This clearly indicates the growth of the laser industry and the attendant increase in enforcement responsibilities. This growth combined with the complexity of the standard, necessitates that our major enforcement efforts be to educate manufacturers. Our efforts have resulted in 4 compliance cases requiring 4 manufacturers to retrofit products to bring them into compliance.

In support of the Bureau's efforts, our staff has trained four FDA field personnel to be knowledgeable in the regulatory aspects of the standard and in the technical expertise required to field test laser products. These persons are:

1. John Galli who is located in Boston and covers Regions I - III;

2. James Frye who is located in Cincinnati and covers Regions IV - VII;

3. James Chandler who is located in Los Angeles and covers Region VIII and Arizona and Southern California in Region IX; and

4. Robert Stohl who is located in San Jose (San Francisco District) and covers Northern California and Nevada in Region IX and all of Region

These Electro-Optics Specialists (EOS) conduct inspections of manufacturers' records, test products in user locations, and participate with BRH personnel on plant inspections. Each EOS is equipped with 5 kits containing 16 instruments, and associated accessories totaling 240 pounds. Each set of instrumentation is worth about $20,000. This diversity of instrumentation allows EOS to measure nearly all types of laser emissions and some collateral radiation emissions. Presently under development in the Bureau's laboratories are programs to extend the field measurements capabilities to cover unusual and sophisticated products continually being introduced into commerce. Studies are also being made to add new test equipment to the field kits that will both consolidate the kits and simultaneously extend the measurements capabilities of the field personnel.

In addition, 25 power meters have been ordered for FDA field and State use. These instruments, to measure CW He-Ne outputs of up to 5 mW should be available to the FDA offices by October 1977.

Our experience in the administration of the laser standard indicates that some provisions need to be amended. The modifications under consideration would further clarify the standard without affecting the hazard classification scheme and would reduce, in most cases, the burden on affected manufacturers without compromising the public health.

We are proposing to make the definition of "human access" less restrictive, to specify a solid angle for measuring the radiant power or radiant energy and for measuring scanned laser radiation, and to specify a minimum distance for the radiance measurement. Additionally, there is a need to provide for some products, amendments that take into account the probability of viewing the laser radiation or the physical limitations of the eye in following a rapidly moving laser source. A change is also proposed to allow manufacturers to use alternate wording in some of the warning labels.

A Notice of Intent briefly describing these proposed amendments was published in the FEDERAL REGISTER on April 1 of this year. In a separate mailing we forwarded a document containing the actual proposed changes to the standard including the rationale for those changes. Both documents were mailed to all known parties interested in the laser standard. The proposed changes were presented in May to TEPRSSC, which essentially supported all the amendments with some minor provisions. The next step will be to publish the change in the FEDERAL REGISTER as a proposed rule.

I should point out that many who commented on the proposed amendments suggested that we incorporate other changes to the standard at this time. Because of time constraints we could not adequately review these proposed changes before the TEPRSSC meeting. We will, however, consider all of their proposed changes along with others we have in mind for further amendments to the standard.

With respect to lasers used in light shows, the Bureau is seeking concurrence by General Counsel to apply the FDA laser product performance standard to laser light shows used by touring rock groups. The standard would be applicable to (1) any laser product manufactured after August 2, 1976, which is either sold by its manufacturer for use as a light show or modified by a rock group or its agent for such use; and (2) any laser system assembled by a rock group or its agent after August 2, 1976, for use as a light show, including the setting up of the total system (scanners, mirror balls, and so forth) before each show. Such light shows would be considered "demonstration laser products" which must not permit human access to laser radiation above the limits of Class II as applicable to either scanned or stationary beams. Furthermore, all viewable laser radiation from display screens or other viewing optics would have to be less than the limits of Class I where viewed. The Working Group on Suggested State Regulations for Lasers has been meeting since May 1976 to complete work, with support of BRH staff, on a set of model regulations for use by the States in the "light" area.

This working group (Jack Rogers, Frank Bradley, and Joe Thiel) has also become concerned with the increasing use of lasers in light shows and by rock groups without adequate radiation control. They have been considering how the provisions of these model laser regulations might be used by the State and local radiation control programs to control the potential hazards of these light shows. They are in the process of preparing guidelines to accompany the model laser regulations, as an appendix, to assist in identification and interpretation of those provisions that would apply to control of the use of lasers in light shows and by rock groups.

A performance standard for sunlamps has been under development for a couple of years. Its publication as a proposed rule in the FEDERAL REGISTER is eminent. A sunlamp product would be subject to the proposal if it is a nonprescripton electronic product designed to incorporate one or more ultraviolet lamps, and intended for irradiation of any part of the living human body by ultraviolet radiation within a range of wavelengths from 180 through 320 nm to induce skin tanning or otherwise affect the structure of any function of the body. Ultraviolet lamps subject to the standard are those that produce radiation within a prescribed range of wavelengths and that are intended for use in sunlamp products.

The standard is intended to reduce the possibility of sunlamp-related injury by minimizing unnecessary exposure and overexposure (especially those overexposures that produce burns) to sunlamp radiation. This will be achieved through provisions in the standard that limit shorter wavelength emissions which pose unreasonable risk, provide for more adequate label warnings and user instructions containing safety information, and require special lamp bases, protective goggles, timers, and controls to help users limit the duration and amount of exosure.

The Bureau has had one compliance action involving defective sunlamps. In April of this year, the General Electric Company informed the Bureau that they discovered some timer failures in their Model RSK6 "Time-A-Tan Suntanner" kits, manufactured between January and March 1977. The kit consisted of a sunlamp, sunlamp holder with timer, goggles, and an information booklet.

The sunlamp is activated by turning the timer switch to the desired exposure time (maximum 10 minutes), and is automatically turned off by the timer when the preset exposure time is reached. A buzzer is automatically sounded about 1 minute before turn off. G.E. found during a regular quality control inspection that in some of the lamp holders the timer fails to sound the buzzer and switch off the sunlamp at the preset time. This results from the disengagement of the motor drive from the timer switch because the two parts of the timer device were not fastened securely. Users could therefore be overexposed to ultraviolet light and severely burned if they are not aware the timer is malfunctioning.

The General Electric Company suspended production and recalled all kits from the distribution system. Approximately 14,000 units were manufactured between January and March 1977. In addition, a press release was issued asking consumers to return the lamp holders, whether faulty or not, for a free replacement.

Another action that the Bureau has taken regarding sunlamps has been to ask two manufacturers of sunlamp products to discontinue the production of sunlamp holders without timers. The Bureau is very concerned with the public health ramifications of this situation, since a definitive means of timing and terminating sunlamp exposure would aid consumers in reducing the possibility of overexposure. There will be a proposed timer requirement in the forthcoming sunlamp performance standard, but since much of the industry has already voluntarily taken positive steps to include a timer, the remaining manufacturers are being asked to take this step also.

FDA plans to develop consumer information on sunlamp products. We will issue in the near future messages intended to caution manufacturers, distributors, purchasers, and users about the hazards associated with the use of ultraviolet lamps, and particularly those sunlamp products and UV lamps intended for cosmetic or tanning effect, and not used under medical supervision. They will be informed about the Agency's plans to issue a regulatory performance standard applying to the manufacturer of these products.

In addition:

(1) Manufacturers and distributors will be urged to market only sunlamp products that are equipped with timers and appropriate warnings and instructions on safe use. Also, an ultraviolet lamp intended for use with a sunlamp product should be accompanied with warnings that it should only be used in a fixture supplied with a timer, and proper user instructions; and

(2) Purchasers and users will be cautioned against the use of a sunlamp product not equipped with a timer. Users will also be cautioned about serious injuries unless the sunlamp product is designed for human exposure, and is provided with appropriate user instructions. For example, the need will be stressed to limit the exposure time and distance, to wear protective eyewear, and to make appropriate allowances for unusual skin sensitivity under certain conditions.

BRH concern for sunlamps in health spas is only one part of the overall concern for sunlamp safety. As with any sunlamp, for example, sunlamps used in health spas should incorporate some form of a timer. In fact these products should not be used without timers, yet we know that health spa installations do not necessarily have timers. Another concern we have is that goggles may not be available to users of sunlamps in health spas--the admonition to the user to close his or her eyes appears to be the only way of providing eye protection in some health spas.

What are we doing about these problems? In terms of product performance, we are proposing a regulation that would require the products to incorporate timers, to contain goggles, and display warnings. From the product performance standpoint, then, we have done things that will be protective of public health. With respect to units already out in the field, and this includes all sunlamps not just those in health spas, the major thrust as I mentioned previously, is to be directed at educating the consumer who either uses his own sunlamp or uses one at a health spa. The use of timers, goggles and common sense will be the central theme of the campaign. Of course, health spas should be told additionally about the need for safe maintenance procedures and the need for posting instructions for use of timers, goggles and common sense in the "sunlamp."

In view of the continuously reported injuries from damaged mercury vapor lamps, FDA issued the proposed radiation safety criteria for such lamps in the FEDERAL REGISTER on October 8, 1976, and at the same time issued a Notice of Intent to develop a regulatory standard, inviting public comments on the criteria and submittal of information concerning the regulatory approach. Over 200 letters of comment were received. Most comments were from lamp manufacturers, utility companies, and municipal governments, including a National Rural Electric Cooperative Association and a local municipal league. A major objection to the proposal was that the criteria apply to all types of mercury vapor lamps for general illumination regardless of their applications. Their objection was based on economic considerations and the fact that almost all reported incidents have been indoors. Because of these comments FDA has decided to accept the two-lamp concept; one incorporates some self-extinguishing device, and the other does not. As a result of this new approach, FDA has also decided, instead of finalizing the proposed safety criteria, to develop a regulatory standard in order to assure a more effective control of such products. This approach was reviewed at the 15th meeting of TEPRSSC held in May 1977. The standard is expected to be published in the FEDERAL REGISTER as a proposed regulation before the end of this year.

After a careful review of the comments in response to FDA's proposed criteria and ANSI's standard published in November of 1976, FDA has reexamined the issue of the voluntary versus the regulatory approach and concluded that the voluntary approach would not be sufficient to provide adequate protection of the public. The principal reasons we choose the regulatory route are:

(1) A regulatory standard can uniformly require the manufacturers to build the safety features into the products. Consumer protection is more visible under a regulatory standard.

(2) It does not depend on the defect provisions as provided under Section 359 of the Radiation Control Act for its implementation. The enforcement of a regulatory standard is stronger and more effective through review of reports, laboratory testing and plant inspections.

(3) Compliance actions under a regulatory standard deal with violations of standard including labeling, advertising, instructions, and so forth, which are especially important for the safe use of those lamps without a self-extinguishing device incorporated.

(4) It provides better control over imports by use of existing systems designed for products subject to a standard.

FDA has so far received reports of 16 separate incidents. More than 200 persons were injured as a result of overexposure to UV radiation coming from broken mercury vapor lamps. Two incidents reported in the past year are worthy of special mention. One incident took place in November 1969 in a public arena in Springfield, Massachusetts. In this incident, a hole of about a half-dollar size existed on the outer envelope of the lamp; approximately 20 people were injured during the period of 2 weeks before the bulb was removed. The other incident took place in January 1977, in a gymnasium in Trenton, New Jersey. In this case, the hole in the lamp was reportedly about the size of a quarter and 69 people were injured within a period of over 3 weeks during which the damaged lamp continued to operate. Because of these incidents, FDA is considering adjusting the 2 minutes extinguishing time as proposed in the radiation safety criteria for such lamps to a cutoff time that would permit a workable design to extinguish the lamp under various damage conditions without adversely affecting the integrity and design life of the lamp and, yet, still provide adequate protection for the public.

With regard to informing consumers, the FDA plans to issue in the near future messages intended to caution purchasers, users, architects, and others responsible for design of exterior and interior lighting, about the hazards associated with damaged high-intensity mercury vapor lamps. They will be informed of the Agency's plans to issue a regulatory performance standard applying to the manufacture of these products.

In addition:

(1) The Agency will recommend that special precautions be taken in the design and construction of indoor or exterior lighting for areas in which people may be exposed for extended periods such as a gymnasium, warehouse, or public athletic arenas and auditoriums. These areas should be provided with indirect lighting, if mercury vapor lamps are to be used. Alternatively, the fixture should be provided with shields to protect against damage to the outer glass envelope of the mercury vapor lamp; and

(2) The purchasers and users of mercury vapor lamps will be informed about the ultraviolet hazard associated with a damaged but still burning mercury vapor lamp, particularly if the lamp may expose people for extended periods. Lamps used in public places should be periodically inspected for signs of damage, and replaced with a lamp which has a self-extinguishing feature.

DISCUSSION

MR. SMITH (Oklahoma): My question is directed to Mr. Copeland and Dr. Bradley. In view of the potential for damage from the laser light shows, the non-benefits other than entertainment, have you considered banning such exhibits altogether?

MR. COPELAND: In answer to your question, yes, we have considered doing that. However, we find, in talking with the legal people in our department, that it is very difficult to write a set of regulations to apply to a specific group of users in our State. They feel that any regulations that we write should apply to all users of a particular device; in other words, we might be accused of tending to discriminate if we singled out that particular application and said we would not allow that. So, what we are trying to do now is devise a method whereby they could be controlled by other means.

DR. BRADLEY: I think it would be difficult to ban the use of lasers if it is being used safely.

STATUS REPORT - NRC/EPA TASK FORCE ON EMERGENCY PLANNING

Harold E. Collins
Assistant Director for Emergency Preparedness
Office of State Programs, NRC

The commercial nuclear power industry has expanded greatly in the last several years and is expected to increase as more plants are built to help fill the energy gap in the United States. To date, the industry has maintained an excellent safety record. The Federal Government recognizes this excellent safety record and the efforts by the nuclear industry to continue to reduce even further the probability of accidents. However, it also recognizes that the probability of an accident involving a significant release of radioactive material is not zero. It has been and continues to be Federal policy to adopt a prudent attitude with respect to the latent potential of these facilities for the release of radioactive materials in hazardous quantities into the environment. Such emergency situations are the focus of attention of Federal radiological emergency preparedness activities, which should contribute further to the overall reduction in risk to public health and safety.

The salient recommendation of the Conference of (State) Radiation Control Program Directors concerning emergency preparedness, which was transmitted to the NRC on June 9, 1976, reads as follows:

> "That the U.S. NRC make a determination of the most severe accident basis for which comprehensive radiological emergency plans should be developed by the offsite agencies."

Additionally, correspondence was received independently from a few States, and in one or two instances from a local government, relating to the foregoing basic recommendation.

In August 1976, a Task Force consisting of NRC and EPA representatives was formed for the purpose of addressing this Conference recommendation and peripherally related issues. We have interpreted this recommendation as a charge to provide a clearer definition of the types of radiological accidents that States and local governments should plan for and develop preparedness programs to support. In addition to this task being prompted in large measure by the Conference recommendation and the recommendations of several representatives of State and local government agencies concerned with radiological emergency preparedness activities, the task also stems partly from perceived differences and ambiguities in various emergency planning guidance activities which have been fostered by the NRC, EPA, and other Federal agencies, and partly by inference derived from the Reactor Safety Study published in 1975 (Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants, U.S. Nuclear Regulatory Commission, WASH-1400 (NUREG-75/014), October 1975). This has led to some apprehension on the part of some States as to the scope and extent of resource allocations in this area which are considered necessary by the Federal government. The principal thrust of this concern relates to those activities which are licensed by the NRC, primarily nuclear power plants.

Since the work of this interagency Task Force has not yet been completed, I am in a position of providing the members of this Conference with a status report on the approach being taken by the Task Force in its deliberations.

One of the first things the Task Force undertook, was an examination of various rationales for establishing an improved planning basis. Four rationales were examined: A risk rationale; a probability rationale; a consequence rationale; and a cost-effectiveness rationale Various pros and cons for each of these were discussed.

With respect to the risk rationale, as quantified by the product of probability and consequences, an approach of this type would establish "planning guidance" which could be compared or correlated with the risks associated with other non-nuclear accidents. Factors favoring the adoption of this rationale would seemingly give a uniform basis for emergency planning for all types of disaster and would clearly indicate the level of risk that we are attempting to avoid. Factors arguing against this rationale center about the lack of evidence that present emergency planning for non-nuclear accidents is correlated to a quantitative risk and there is no data base to support this methodology. Further, such a risk-related rationale might be construed to imply the acceptability of such a risk level which is beyond the intent and scope of the Task Force objective.

With a respect to a probability rationale, one could arrive at "planning guidance" by selecting an accident probability below which it would not be considered sufficiently justifiable to develop an emergency plan to support. Factors favoring the adoption of this rationale center about providing a quantitative basis, solely in terms of probability, which could be compared with the probabilities of other types of emergencies for which plans are prepared. Further, it would provide a direct relationship between emergency planning and reactor safety study accident scenarios and would imply some general Federal decision on what probability of an event was worth considering for any future planning. Factors arguing against this rationale are that there is no evidence that present emergency planning is correlated to a purely quantitative probability level and there is no historical data on which to base a purely probabilistic approach. The implication of a generic "probability of an event" appropriate for planning has many general and far reaching implications felt to be outside the scope of the Task Force objective. I would hasten to add, however, that the concept of probability is important. It certainly does have a place in terms of analyzing the consequences of more probable accident sequences and setting some reasonable bounds on the planning basis.

With respect to a cost-effectiveness rationale, the level of emergency planning effort to be expended would be based on an analysis of what it costs to develop different levels of such a plan and the potential consequences that could be averted by that degree of development. Factors favoring the cost-effectiveness rationale are that the emergency plan would be developed on the basis of cost per potential health effect averted and would incorporate a large input data base comprised of consequences; probability as well as financial considerations. Factors arguing against the cost-effectiveness rationale are the difficulty in arriving at precise costs of plan development, and the fact that general and radiological emergency response plans have already been developed to some extent (some being quite complete).

The consequence rationale, would identify an offsite consequence, such as projected radiological doses (rather than an accident mechanism) that could be used as a basis for determining the need for development of emergency planning. A major factor favoring the consequence rationale approach is that the guidance can be developed in terms of consequences of sufficiently broad scope as to type. Using these consequences as an emergency planning basis would provide a capability to expand or contract the planning effort in the case of actual accidents of greater or lesser consequences. Further, guidance, which is in the main consequence oriented, would serve the needs of the States and their local governments without having to get into the broader areas of "acceptable risk" or "probability worth planning for." Consequence-oriented guidance would provide for uniformity in the amount of planning required by the States and is the approch several States have taken or are taking. The disadvantage of relying on the consequence rationale exclusively is that the choice of the consequence level would appear arbitrary and without technical basis.

There is a requirement for each nuclear facility to have an emergency plan supported by offsite organizations. Through already published Federal guidance, there is an a priori recommendation that States and local governments should formalize their emergency response plans in support of these facilities and to protect the public health and safety offsite. With this being the case, the efforts of the Task Force have been focused on improving guidance in terms of basic types of consequences that offsite organizations should be able to handle.

In developing a rationale for the selection of a planning basis, it was realized that there was no specific accident that could be isolated as the one for which to plan, because each accident could have somewhat different consequences, both in nature and degree. In light of these facts, a "worst case" accident situation cannot be identified or characterized and associated with firm protective action guidance such as to form a sole basis for planning protective measures for all possible consequence pathways. The Task Force is considering a set of consequences which do not describe those of a specific nuclear power plant accident. They are a composite of possible consequences from a variety of accident scenarios, at a level considered adequate to require response planning, which involves at least a nucleus of all State and local emergency response components. A selection of the magnitude of the consequences will involve an element of judgment supported somewhat by probability considerations. The types of activities and organizations being considered in this evaluation include law enforcement, civil defense, public health, transportation, radiological, public service, fire and rescue, and others. With such involvement in the planning stage, it is felt that there will be a base established that will allow the maximum flexibility on contracting from or expanding on this base as may be required by the conditions resulting from an actual accident.

The elements needed to describe the planning basis for radiological emergency response plans have been identified by the Task Force as (1) the size of the planning area; (2) the time dependence of the release; and (3) the radiological characteristics of the release. A fourth element, the demography of the area was identified, which is site specific and cannot be addressed in general guidance. State and local officials must consider demography and any other site specific parameters on a case-by-case basis.

The size of the planning area is influenced in great part by two basic accident phases--the emergency or immediate phase--and the intermediate phase. The emergency phase is defined as the period during and following an atmospheric release when the principal exposure pathways are (1) whole-body external exposure to gamma radiation from the plume and from deposited material and (2) inhalation exposure from the passing plume. The emergency phase ends when emergency protective actions such as shelter and/or evacuation have been completed or decisions have been made that they are not needed. This phase would generally have a duration of hours to days. The intermediate phase is defined as the period following an accident when the principal exposure pathway would be from ingestion of contaminated water or foods such as milk or fresh vegetables. This phase would generally have a duration of hours to months. The Task Force has not yet arrived at a consensus with respect to the size of the immediate and intermediate phase planning areas except that it has determined that the latter planning area is substantially larger than the former.

The time dependence of the release influences the planning basis with respect to implementing any required protective measures. The Task Force is identifying time ranges from less than one hour to several hours and relating these ranges to the sequence and nature of the radiological release. Warning time ranges, continuous release periods and time ranges for major portions of the release are being quantified to provide a planning basis in terms of planning the implementation of various protective measures.

The radiological characteristics of the release influence the planning basis in terms of estimating projected doses, identifying critical exposure pathways and critical organs, and deciding what kinds of monitoring instrumentation should be available to assess the nature and extent of the radiological release itself. The Task Force is of the opinion that information concerning the characteristics of the release should be a part of the guidance it is developing and is identifying release characteristics including a list of the most significant radionuclide groups.

Finally, the Task Force has been reviewing a great deal of supportive information from the Reactor Safety Study, the Design Basis Accidents analyzed for siting purposes, siting criteria, and other relevant materials which has been valuable in determining our approach toward the development of a clearer planning basis. I am of the opinion that the prognosis is good for preparing a report that both NRC and EPA can adopt and that contains improved planning basis guidance. This should be a major step forward in our efforts to assist the States and their local government in the emergency planning area. We intend to provide this Conference's Emergency Planning Task Force an opportunity to review and comment on a draft version of the report in the near future.

DISCUSSION

DR. SLOAN: Are you saying that your group is leaning toward consequence-oriented response?

MR. COLLINS: Yes. If it did not come out in my talk, I think I brought it up twice, but since I talked about so many rationales, it may have gotten lost in the shuffle. The last one I did talk about was the consequence rationale. The tack that we are taking is with the consequence rationale, flavored slightly with probability considerations, but not flavored to the degree that it becomes a risk rationale. In other words, a risk rationale depends heavily on the product of consequence and probability. And we are not going down that route entirely. We are basically pursuing a consequence rationale flavored very slightly with a probability consideration. I think that it is safe to say that we are proceeding along those lines.

ACTIVITIES OF THE ATOMIC INDUSTRIAL FORUM OF INTEREST TO STATE PROGRAMS

E. David Harward
Environmental Projects Manager
Atomic Industrial Forum, Inc.
Bethesda, Maryland

It is a real pleasure to have the opportunity to meet with old friends and to discuss some of the technical activities in the environmental area conducted by the Atomic Industrial Forum.

The Atomic Industrial Forum is a not-for-profit international management association representing over 600 member organizations, including electric utilities, manufacturers, architect-engineers, consulting firms, uranium mining and milling companies, universities, legal firms, and individuals. The Forum is interested in the peaceful uses of nuclear technology and works to support the public's needs for nuclear energy; it tries to solve and prevent problems facing the peaceful applications of nuclear energy. Toward these ends, the AIF provides a forum for its member groups to arrive at a consensus opinion on policy and generic technical issues, provides a mechanism for the industry to interact with the government, and collects information for the industry, the mass communications media, and the public. Often, the Forum is invited to provide testimony on key issues before Congressional Committees and Federal agencies.

The Forum is generally organized into a technical program and a public affairs and information program. There are several components making up the Forum's technical program; the Technical Department, headed by a Vice President, includes managers for environmental projects, reactor safety and licensing, reactor construction and operation, the National Environmental Studies Project, and an environmental information clearinghouse utilized by both the industry and regulatory agencies that is called INFORUM. In addition, the Forum's Executive Vice President has a program manager for nuclear fuel cycle services projects and one for special projects which include such subjects as proliferation and fusion.

Of special interest to you, I believe, are the Forum's environmental programs, particularly those related to radiation protection. First, I would like to discuss the Forum's activities in the environmental projects area. These are generally carried out by a Committee on Environment which consists of a Steering Group and approximately 120 Forum member representatives participating on a number of ad hoc problem oriented working groups. These working groups carry out their activities under the overall policy guidance of the Steering Group. I would like to give you a brief summary of some of the current working group activities which are of particular significance and will serve as examples of our program activities.

The Working Group on Occupational Radiation Exposure has been in existence for the past year and has been engaged in several projects, most notable of which has been a project with the Nuclear Regulatory Commission staff in the development of proposed regulations pertaining to the protection of transient workers. The current NRC regulations are in need of some revision in order to adequately protect this segment of the working population that is now increasing as more nuclear plants become operational. In an effort to obtain information on which to base possible changes in their regulations, NRC requested the Forum to examine the actual practice of recordkeeping for transient workers to provide input into their value impact analysis. Our efforts focused on transient workers moving among nuclear plants and we requested cost-benefit information from the operating utilities. We compiled this information for the NRC in order to provide them with a better technical basis for proposed changes. The basic problem is how to ensure, in a cost effective manner, that the worker going on to another licensed facility has an adequate exposure record. The data obtained in our survey and recommendations by the working group will be utilized by NRC in their determinations.

Another recent activity of significance has been carried out by the Working Group on Environmental Reports, a committee that was established several years ago. In addition to providing the Nuclear Regulatory Commission with detailed comments on its revised Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," this group as well as several other committees has been reviewing the draft of the NRC's Environmental Standard Review Plan. This plan will form the basis for NRC staff environmental review of applicants' environmental reports and will, likewise, formulate the basis for the requirements for submissions by applicants requesting construction permits and operating licenses. The goals of the NRC plan include the reduction in duplication and paperwork, and the elimination of unnecessary information in the EIS process. This is also an announced goal of President Carter and his Council on Environmental Quality. Earlier this month, the Forum Committee on Environment testified at CEQ hearings on streamlining the EIS process and suggested ways of improving this process based on 7 years of experience with NRC procedures, probably the most advanced of the Federal agencies.

When the Nuclear Regulatory Commission announced its findings on Appendix I of 10 CFR 50, numerical guidance for "as low as reasonably achievable," they also announced that every effort would be made to make the implementation requirements meaningful and realistic. However, when NRC Regulatory Guide 1.111, "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors," was issued, meteorologists in the industry sector felt that some of these requirements were not necessarily realistic and, in some cases, were overconservative. A Working Group on Atmospheric Diffusion was formed to review this guide and to work with NRC in seeking a more realistic approach. One of the outcomes of the work of this group has been a cooperative effort with the Electric Power Research Institute (EPRI) in defining research and development programs in the meteorological area which would meet NRC's needs in modifying certain overly conservative provisions of the Regulatory Guide. These studies are now under development by EPRI. This group has also been quite active in reviewing the diffusion portions of the NRC Environmental Standard Review Plan.

Two other Working Groups have been heavily involved in participating in the review of the NRC Environmental Standard Review Plan - the Biological Sciences and the Socioeconomic Impact Working Groups. These Groups are composed primarily of member representatives having expertise in these particular fields, and have been able to incorporate practical experience in their input to NRC on the content of the Environmental Standard Review Plan in the ecological and socioeconomic impact areas.

Last year, a small ad hoc Working Group was established to examine environmental radiation aspects of the uranium mining and milling industry to determine what, if any, industry initiatives were needed to resolve possible future environmental problems in this segment of the nuclear industry that might impact on the overall licensing process. A committee was formed consisting of representatives from the mining and milling industry, utilities, a consulting firm, and a radiation measurement equipment manufacturer. This group initially met with representatives of the Environmental Protection Agency, Nuclear Regulatory Commission, and Energy Research and Development Administration in establishing the extent of environmental studies being conducted by these and other agencies at both the Federal and State levels. As it turned out, there were an extensive number of studies underway and there seemed to be a need for additional coordination among the Federal agencies involved. This meeting resulted in the agencies meeting at a later date to coordinate some of the technical aspects of their activities. One of the outgrowths of this Committee and the meeting with those agencies was recognition of a need for a workshop that would allow individuals involved in environmental radiation measurements in the vicinity of uranium milling operations to discuss their mutual problems associated with analytical techniques and to see if better environmental radiation data comparability could be achieved. This need was at least partially fulfilled when the Forum, in cooperation with the Energy Research and Development Administration, the Environmental Protection Agency, the American Nuclear

Society, and the Health Physics Society held such a workshop in Albuquerque, New Mexico this past May. The high interest in this subject was reflected by the outstanding attendance at this workshop, representing all sectors of the industry, government and academia. I should add that it was well attended by representatives from States.

One of the long-standing Working Groups has been that on ALAP and Radiation Releases. This particular group has been involved with a technical examination of the Appendix I determinations of the Nuclear Regulatory Commission and the uranium fuel cycle standards (40 CFR 190) proposed and now promulgated by the Environmental Protection Agency. This group will continue its activities in the environmental radiation protection area with a continuing review of the EPA efforts on the development of standards and criteria for radioactive waste management. Activities of this group are coordinated with another Forum Committee on Waste Management and a separate utility group looking at the overall problem of radioactive waste disposal.

In other related activities, working groups are involved in reviewing the Environmental Technical Specification question with the Nuclear Regulatory Commission with a specific objective of eliminating dual regulation between NRC and the EPA and/or States in the enforcement of non-radiological limits at operating nuclear power plants. This effort has been somewhat successful in that NRC may be requiring NPDES permit limitations from licensees as information items as opposed to being enforcement items. This issue was complicated by the changing nature of NPDES limits approved by EPA or States and the delays involved in getting the amendments also approved by NRC.

In another area, the Forum periodically sponsors conferences on various subjects related to nuclear energy, including environmental programs. In addition to the uranium mill related workshop mentioned earlier, a 3-day conference on nuclear facility siting and land use planning was held last summer in Denver. The next environmental conference will be held this coming October in Washington and will deal with environmental regulatory issues associated with nuclear power facilities.

Next, I would like to describe the activities of the Forum's National Environmental Studies Project (NESP). This project was created by AIF in 1973 for the express purpose of conducting generic contact studies of technology, methodology and practices concerned with the environmental impacts of nuclear energy. This project has been especially oriented to those studies that apply to the reporting requirements of Government regulatory agencies pursuant to the implementation of their responsibilities under the National Environmental Policy Act.

The National Environmental Studies Project is supported by more than 100 member organizations and, since its inception, has published 13 reports based on 10 studies--some quite broad in scope and others highly specialized. Topics have ranged from decommissioning of nuclear power plants, low level waste handling, and occupational radiation exposure to power plant siting methodologies and socioeconomic impact assessment. These studies have been referenced in NRC and EPA documents and have been used extensively in hearings before the NRC, EPA and State regulatory groups. Federal agency participation is an integral part of most of the studies' development, implementation, and technical review. A spinoff from NESP, that has grown in sufficient stature to take on its own identity, is a project called INFORUM, which serves as a central technical/environmental information clearinghouse for both the nuclear industry and regulatory agencies.

A list of completed, on-going, and anticipated NESP studies is included as an attachment to this paper, and will be available in the transcript. However, I would like to mention several of the studies which I think are of particular interest to this group. These reports are available to the public at cost from AIF.

A major study was completed recently entitled, "An Engineering Evaluation of Power Reactor Decommissioning Alternatives." This report was nearly 2 years in preparation and represents one of the initial efforts at defining costs, occupational radiation exposures, and environmental impact of decommissioning a nuclear power plant, and is based on previous experience. Although there is much work needed to be done in evaluating the overall decommissioning problem, this effort has estimated the costs of decommissioning by several alternative methods. Of the five alternatives considered, the study found that the most cost-effective means would probably involve a combination of mothballing for a period of 65 to 100 years to allow radioactive decay, followed by removal/dismantling of components.

Another report of particular interest to this group is a recently completed study entitled, "A Survey and Evaluation of the Handling and Disposal of Solid Low-Level Nuclear Fuel Cycle Wastes." This study utilized up-to-date information from operating nuclear power plants, and summarized existing waste quantitative and qualitative information and made projections of possible future waste volumes that would have to be handled by the Nation's shallow-land radioactive waste burial sites. One of the conclusions of the study was that the volumes of low-level waste were likely to be higher than predicted and that efforts should be made to utilize better volume reduction techniques at the power plant site.

One of the earlier studies was a gas tracer study of roof vent diffusion at the Millstone Nuclear Power Station. This study resulted in some improvements in atmospheric diffusion models for routine releases of radioactive effluents to the atmosphere that have been used by NRC in guidance for implementing Appendix I.

A report entitled, "Compliation and Analysis of Data on Occupational Radiation Exposure Experienced at Operating Nuclear Power Plants," identifies the major sources contributing to occupational radiation exposure and compiles the radiation exposure associated with certain sources during operation and maintenance.

A set of reports entitled, "Environmental Impact Monitoring of Nuclear Power Plants - A Source Book of Monitoring Methods," was developed and published in 1975 and have been useful in providing guidance on methodologies for various aspects of monitoring including ecological and radiological.

I have mentioned a representative but incomplete list of published NESP studies. Current programs include an effort to quantify ALARA for occupational radiation exposures by developing a methodology for calculating the site-specific costs of incremental occupational radiation exposure as they relate to certain refueling/maintenance operations in operating nuclear power plants. Also in the occupational radiation exposure area is a study to demonstrate the feasibility of maintaining a computerized data base which relates exposures to worker type, work activity, and plant systems and components. This is being done on a trial basis with participating utilities to supply summarized data that will be used to improve in-plant exposure management programs, show compliance with ALARA, and improve future reactor designs.

Another study now underway is entitled, "Migration of LWR Radwastes from Shallow-Land Burial Grounds and an Evaluation of Concentration Limits for the Shallow-Land Burial of Transuranic Contaminated Low-Level Wastes." This study is for the purpose of developing a methodology for estimating radiation doses to the public asociated with shallow-land burial of non-transuranic contaminated low-level LWR wastes. As part of the same program, but to be published as a separate report, is the development of a methodology to evaluate low-level burial concentration limits for transuranic contaminated waste in order to help define criteria for future burial of such waste.

The possibility of detours being imposed for the shipment of spent reactor fuel has resulted in a study of the environmental impacts of intermodal/Water Modes transportation. This study is to determine the relative importance of the various problems associated with the transport of spent nuclear fuel by these means as well as the radiological impacts on the public and workers involved in transportation by these methods.

The last study I will mention is being co-sponsored with the Edison Electric Institute in cooperation with EPRI on a state of the art review of the economic and social effects of energy facility construction. This is becoming more of a problem where large facilities are located in more remote areas and impact on smaller communities having limited support facilities.

The final subject I would like to discuss is the Forum's environmental information service called INFORUM. This project provides ready access to the wealth of information submitted by utilities and their consultants to State and Federal regulatory agencies in the form of environmental reports and studies. The office maintains a complete set of all environmental reports and environmental impact statements for nuclear and fossil fuel power plants as well as Section 316(a) and (b) demonstrations submitted by the various utilities to the 10 EPA regions and a variety of State Water Pollution Control Boards under the Federal Water Pollution Control Act. This information is coded for computer input and stored for future retrieval. The newest abstracts are published on a bimonthly basis in a technical journal available by subscription and indexed according to geographic location, subject, author, and NEPA requirement. In addition to the publication, the project performs a custom search service for specific information requests and publishes a Section 316 statistical index of power plants and utilities involved in the Section 316 process. This list is updated semiannually by the regional permit officials and approximately 10 State officials for the INFORUM staff. The project receives its funding from the National Environmental Studies Project, the Electric Power Reseach Institute, the U. S. Energy Research and Development Administration, and through sale of its publications and services to Forum members.

ATTACHMENT

Current Programs of the Atomic Industrial Forum National Environmental Studies Project

Demonstration of a Computerized Data Base for Occupational Radiation Exposures. NESP is demonstrating the feasibility and practicability of maintaining a computerized data base which relates exposures to worker type, work activity and plant systems and components. Participating utilities with operating plants will contribute summarized data which may be used to improve in-plant exposure management programs (compliance with ALARA) and future reactor designs.

Quantification of ALARA for Occupational Radiation Exposures - Economic Considerations. Nuclear Environmental Services Division of Science Applications, Inc. is developing a methodology for calculating the site-specific costs of incremental occupational radiation exposure as they relate to certain refueling/maintenance operations in operating nuclear power plants. Scheduled to be completed in Fall, 1977.

Migration of LWR Radwastes from Shallow-Land Burial Grounds and An Evaluation of Concentration Limits for the Shallow-Land Burial of Transuranic Contaminated Low-Level Wastes. Dames and Moore is developing a methodology for estimating radiation doses to the public associated with shallow-land burial of non-transuranic contaminated low-level LWR wastes. As part of the same program, but to be published as a separate report, D & M is also developing a methodology to evaluate low-level burial concentration limits for transuranic contaminated waste in order to define criteria for future burial of such waste. Scheduled to be completed in late Summer 1977.

Economic and Social Effects of Energy Facilities Construction and Operation-State-of-the-Art-Review. Jointly sponsored with the Edison Electric Institute, Westinghouse Environmental Systems Department is describing current practices for socioeconomic impact assessment, monitoring and management of large energy facility projects (nuclear and fossil). Scheduled to be completed in Summer, 1977.

Intermodal/Water Transportation of Spent Fuel. Science Applications, Inc. is determining the relative importance (risk assessment) of problems associated with transporting spent nuclear fuel by intermodal/water modes (IM/WM). The radiological impacts on the public and on workers involved in transportation by IM/WM, as well as the economic feasibility, are being assessed. Scheduled to be completed in Summer, 1977.

Potential Future Studies

De Minimus Levels of Plant Effluents. To establish criteria and to develop a generic methodology that can be used to determine de minimus levels of contamination that are acceptable for the unrestricted disposal of spent filter-demineralizer resins. These resins generally contain very low levels of radioactive contamination, if any, and therefore, should not necessarily require radwater processing and disposal in licensed shallow land burial grounds. The issue is that there currently exist no guidelines or criteria which establish acceptable levels of radionuclides above which the resins must be processed and disposed of as low-level reactor waste, and below which the resins may be safely disposed of in an unrestrictred manner. It is also intended that the generic methodology developed in this study will, to the extent possible, define the criteria and identify the dose pathways to man that are applicable to the unrestricted disposal or release of other slightly contaminated solids and liquids and gasses.

Methodologies for Evaluating the Effects of Closed-Cycle Cooling Systems. To identify the scope and detail necessary in the assessment of cooling tower effects in order to comply with NRC Regulatory Guide 4.2 requirements. It appears that current assessment of cooling tower effects that utilities submit to the NRC in Environmental Reports are considerable beyond those required. It is intended that this study would provide information for NRC's consideration in its revision of Regulatory Guide 4.2.

Quantification of ALARA for Occupational Radiation Exposures - Phase II. Although the specific subject of Phase II of NESP's continuing efforts in this very important area will be determined by the Task Force after completion of its current work, a study of reactor decontamination is an appropriate and timely topic. The results of a study on decontamination in conjunction with NESP's current Quantification of ALARA-Phase I work--"estimates of the economic costs of incremental occupational exposures"--would provide utilities with some measure of the cost-benefit balance of routine decontamination procedures during plant refueling/maintenance outages.

On-Site Low-Level Waste Management Alternatives. To investigate the engineering feasibility, economics, generic environmental effects, and regulatory aspects of storing and disposing of low-level LWR wastes at the reactor sites. In particular, the study will focus on two on-site alternatives, which are long-term storage in structures and disposal by shallow-land burial. Waste volume reduction and solidification technologies will be considered. The study will also consist of an abbreviated literature review of other on- and off-site alternatives for LWR low-level waste disposition. It is intended that the results of this scoping analysis will provide the nuclear industry with sufficient generic information to determine whether or not certain on-site storage and disposal alternatives merit further consideration as LWR low-level waste management options.

Economic and Social Impact Assessment - Phase II. The relatively high priority standing that this study topic received from those NESP sponsors who submitted evaluations of NESP's activities strongly supports a continuation of work in socioeconomics. However, until the current socioeconomic project with EEI, EPRI and Westinghouse is complete and the industry has had an opportunity to review the results, the exact subject for Phase II should remain open.

INFORUM

Description: Technical, environmental effects information service which provides indepth abstracting and indexing of specialized studies and data contained in environmental reports and statements (ER's and EIS's) for energy facilities. Until recently emphasis placed primarily on ER's and EIS's for nuclear power plants; in early 1976 added specialized studies for Section 316(a) and (b) demonstrations concerned with power plant thermal discharges which are submitted to EPA regional offices and State agencies. In September 1976 added fossil-fueled power plants (coal, oil, geothermal, and so forth); uranium mining & milling facilities, coal mining, fuel reprocessing, waste disposal, and so forth.

Coverage: 1970 to Present with newest ER's and EIS's given priority.

Technical Publication: INFORUM, published bimonthly; one issue contains 1,000 newest abstracts added to data base, plus indexes -geographic, author, keyword and NEPA index. NEPA index arranges titles and accession numbers according to requirements of National Environmental Policy Act and NRC Regulatory Guide 4.2. For example, Chapter 4 of this index deals with construction effects on water, air, land, and so forth, Chapter 5 deals with operational effects on water, air, and so forth; Chapter 8 with Socioeconomic Impacts.

Cost of A/I Publication: $350 per year/by volume no. in North America; $395 per year/by volume no. overseas. Includes loose-leaf binder and specialized indexes (EPA 316 Index, U.S. Nuclear Power Plants Index published twice a year) and topical bibliographies spun off from the data base.

Other Publications: Section 316 Index (listing of Section 316 applications submitted under the Federal Water Pollution Control Act Amendments of 1972 by EPA region, State, utility and power plant. Includes status of applications, utility liaisons and other plant data); Topical bibliographies; "Guide to Information Resources for Nuclear Environmental Reporting."

Size of Data Base: 12,000 records.

Availability: At present through INFORUM Custom Search Service and at ORNL where it is accessed by NRC EIS writers. Data base is stored with Computer Sciences Corp.'s INFONET and possibility of on-line searching being considered by AIF.

Services: INFORUM Custom Search Service provides computer searches of INFORUM data base and U.S. ERDA/RECON data systems: ERDA Energy Data Base; Nuclear Science Abstracts; Nuclear Structure Reference; National Referral Center; Environmental Mutagens; Energy R&D Projects; Nuclear Safety Information Center; Chemical Abstracts/Energy; Data Base Survey; Engineering & Environmental Modeling Survey; National Biomonitoring Inventory. Also manual searches of data contained in ER's and EIS's as well as manual search of licensing materials in NRC Public Document Room and other libraries. Photocopying of originals of all items in data base. Usage of INFORUM technical library (containing hard copies of all materials in data base) for subscribers to publication and members of Atomic Industrial Forum.

Cost of Services: Manpower is charged at the rate of $30 per hour. Computer costs, telephone charges, photocopy costs and any other direct expenses are charged separately. Estimates are provided beforehand and a cost ceiling established. Minimum is $50 per request. Charges for ERDA/RECON include AIF manpower and long distance telephone charges only.

DISCUSSION

MS. REILLY: Do you have any handle on what the annual solid waste production at a nuclear power plant would be?

MR. HARWARD: I have numbers in my room, but I do not know offhand.

MR. FUENTE: Is there a writeup of the proceedings in that meeting in Albuquerque?

MR. HARWARD: Yes. It should be available by early fall. (NOTE: Available from AIF, 7101 Wisconsin Avenue, Washington, D.C. 20014.)

SPENT FUEL STORAGE

T. Jerrell Carter
Office of Nuclear Reactor Regulation, NRC

A great deal has been written and said about spent fuel storage. In my talk this morning I do not expect to present any startling new information or conclusions. Rather, I hope to provide a summary of those aspects of spent fuel storage that I believe are interesting and will help you to better understand the spent fuel storage situation and how it relates to nuclear power plants.

Background

In this discussion, "spent fuel storage" means the onsite storage of irradiated fuel assemblies that have been removed from a reactor core. Until recently it was expected that the stored spent fuel would be shipped away from the reactor site within 6 to 9 months after removal from the reactor. Since spent fuel would have such a relatively short residence time at the reactor site, storage capability did not have to accommodate a large amount. Historically, plants have been designed and built with storage pools that have the capability to store fuel discharged during a refueling plus some additional fuel. Generally, the space for additional fuel has been sized for a full core so that if a need to unload the core should occur, space would be available to permit immediate unloading. Therefore, with an anticipated refueling schedule which involves replacing 1/3 of a core, the pool size for a single reactor would be 1-1/3 cores. Reactor sites with two reactors sharing a single pool are likely to have a capability for 1-2/3 cores. Such pools provide storage capability for about 5 years and 3 years respectively, if no fuel is shipped from the site and if means are not used to expand the storage capacity. I will return to this point later.

The NRC does not have a requirement for any particular storage capability. There is no compelling safety basis for requiring a full core reserve. We believe that conditions that might require unloading the core could be permitted to exist and the unloading put off or delayed until space was made available in the pool by shipping stored fuel to some other location. We do not know of any postulated event or safety consideration that requires immediate core unloading. The redundant ECCS and the high integrity of the reactor vessel, especially at the low pressure related to reactor shutdown, provide assurance that cooling and storage of fuel in the core is adequately safe.

In 1974 public interest in spent fuel storage and its impact on reactor operation became more apparent. Articles were written about operational problems that were anticipated because of insufficient spent fuel storage capability. There was speculation about the number of plants that might have to shutdown by the end of the year, or 1980, or whenever. The timing of this interest may be attributed to three things. First, the Government stopped accepting spent fuel for storage from light water power reactors on December 31, 1970. After that time spent fuel generated at operating reactors either accumulated in reactor spent fuel storage pools or was shipped to one of the offsite storage basins. Most of the off reactor site storage capability was reserved for a few utilities that had previously contracted for storage and reprocessing. Therefore, the several years of reactor operation generated sufficient spent fuel to nearly fill the pools at some reactors. Second, there were a number of unexpected fuel failures that caused premature discharge of a large fraction of the core. This discharge increased the number of impacted plants and pointed out that additional fuel failures could jeopardize the operation of many more plants. Lastly, and probably most important, there were delays in bringing commercial reprocessing facilities into operation. The utilities had expected some reprocessing would exist by the mid 1970's and it would take care of the spent fuel. General Electric Company had built the Midwest Fuel Reprocessing Plant but had not started to operate the facility. They subsequently announced that this reprocessing facility was "inoperable" and that it would be closed permanently; it is now being operated as a spent fuel storage facility. Licensing of the new Barnwell facility was being delayed by intervention and design changes. The Nuclear Fuel Services plant in West Valley which was shutdown in 1971 for modification was not operating; NFS is no longer in the fuel reprocessing business. All in all, licensees recognized that there was no panacea on the horizon. They must take positive action to enable their reactors to continue operating.

In the 1973/1974 time period, independent studies by the Nuclear Assurance Corporation, ERDA, as well as NRC, were made of the magnitude of the problem--lack of spent fuel storage capability. The ERDA report (ERDA-25 with updates in 1976 and 1977) is publicly available. The major differences between the studies were the assumptions used in making predictions and hence the specific conclusions. I believe a true and meaningful conclusion reached by all at that time is that some facilities would soon fill their pools and that they would need to do something special to keep operating. The planned reprocessing facilities could greatly assist those first utilities impacted by providing some additional uncommitted storage capability. This offsite storage, however, even with the scheduled reprocessing capability was not seen as adequate for the mid-1980's.

In recognition that something needed to be done, industry discussed several options with the regulatory staff. Three likely possibilities were (1) increasing the capacity of their reactor spent fuel storage pools, (2) constructing and operating independent spent fuel storage pools at reactor sites or away from reactor sites, and (3) transferring spent fuel from a reactor plant with a nearly filled pool to another plant with available storage capability.

In September 1975 the NRC stated that the staff would prepare a generic environmental impact statement on the handling and storage of spent light water power reactor fuel. The Commission also stated that it would continue to act on license applications for increasing onsite spent fuel storage capability while the statement was being prepared. The basis of this decision considered the following: (1) that the possible environmental impact from each such application would be addressed adequately without overlooking any cumulative environmental impact, and (2) such individual licensing action could be justified independently and would not foreclose future alternative action.

As part of the draft environmental impact statement on handling and storage of spent fuel, the short and intermediate spent fuel storage situation was evaluated. The evaluation shows that the storage capability of reactor licensees when taken collectively is and will continue for some time to exceed the cumulative demand for spent fuel storage of all reactor licensees. Therefore, in theory there should be no overall shortage limitation at least through the mid-1980's provided that there is maximum use of available space and licensees continue to increase storage pool capacity. In reality, however, individual licensees are sure to have a filled spent fuel storage pool and may therefore experience difficulty in continuing to operate. Licensees in the future would need to ship spent fuel offsite to spent fuel storage pools with available space. Inter reactor facility transfers, both between units at the same site and from one reactor site to another reactor site, have been reviewed. Only interfacility transfer on the same site has been approved by the NRC; approval for transfer between reactor sites is currently under consideration. Non reactor site storage facilities, such as the General Electric Morris Operation, also provide additional storage capability, and thereby significantly improve the practicality of any fuel transfer program. The fuel storage capacity at the Morris facility was increased to 750 MTU in 1975 and may be further increased to about 1700 MTU in 1980.

Those utilities that had operating nuclear power plants with spent fuel storage pools that were nearly filled and did not have away from reactor storage space committed to them were faced with the possibility of having to shut down the reactor at the next refueling. This would impact the utility's ability to meet the electrical energy needs. This provided the incentive for something positive to be done.

Licensee Action

The first formal proposal for increasing onsite spent fuel storage capability was from Dairyland Power in 1974 for the LaCrosse reactor which was operating with a nearly filled pool. The proposal was to add new racks of a different design to the spent fuel storage pool in "free space." The old racks would remain. This modification would increase the storage capacity from 84 assemblies to 134 assemblies. Since a full core consists of 81 assemblies and about 1/3 of these are replaced during each refueling, the increase in storage capacity should increase operation by at least two refuelings.

Since the LaCrosse application, many other applications have been received. To date there have been about 30 applications and 15 applications have been approved. Legal hearing proceedings for 3 separate applications have been initiated. Table 1 is a listing of applications received, current storage capacity, and size of the requested increase. The requested increase in capacity ranges widely - from 30 percent to 250 percent of the original pool capacity. The median requested increase in pool capacity is 120 percent, or about 1-1/2 cores. The size of the requested increase is the licensees choice. A proposal is made and if our review shows that it is safe, authorization may be granted. NRC does not effect the licensees choice nor do we review the proposal for optimum use of space of any other such consideration.

The cost associated with adding new racks and/or replacing the original racks varies. Most applications show predicted costs that range between $1 million and $3 million. These costs include engineering, licensing, procurement of new racks, and installation. The modification of existing pool capacity provides a relatively inexpensive and quick relief to impact utilities.

Some utilities are looking beyond the modification of storage pools at reactor sites. One utility and an architect-engineer have had preliminary discussions with the regulatory staff to explore licensing and safety considerations of a new and independent storage pool on a reactor site. A group of utilities have discussed their assessment of wide ranging options, including new pools at reactor sites and large regional storage facilities. This group believed that plans need to be made now to accommodate future operation after the additional storage capability of the reactor pools has been used. I am not aware that a decision has yet been made.

One engineering firm has submitted a "topical report" that describes their plans for an independent spent fuel storage facility. This report is presently under review. While discussing independent spent fuel storage facilities, I should mention that the regulatory staff in December 1974 published a regulatory guide 3.24 entitled, "Guidance on the License Application, Siting, Design and Plant Protection for an Independent Spent Fuel Storage Installation."

Technical Review Considerations

I would like to mention some of the technical review considerations and criteria the NRC uses in reviewing an application for increasing onsite spent fuel storage capability. Our review includes both design and accident considerations. Before I begin discussing the technical considerations, I need to mention that the NRC review is not limited to safety considerations. Our review includes an assessment of the environmental impact. Not only are we required by regulations to do this as part of our normal regulatory procedure, but the Commission has stated that until the generic environmental impact statement is prepared, the NRC staff must consider five specific factors having environmental implications. These factors, in addition to other environmental aspects of the modification, are considered in each Environmental Impact Appraisal issued in support of the proposed pool modification.

One design consideration is criticality or reactivity of fuel stored in the new racks. The primary purpose of the racks is to hold the fuel in a subcritical array under all conditions including operational errors, equipment failures and a natural phenomena such as earthquakes.

Table 1. Applications to Expand used Fuel Storage Capacity - 6/1/77[a]

Applicant	Current Capacity	Requested Expansion	Approval
Arkansas Nuclear One	253 Bundles	590	12/76
Beaver Valley 1	272	833	
Brunswick 1 and 2	720 (each)	1386 (each)	
Connecticut Yankee	336	1172	6/76
Dresden 2 & 3	1160 (each)	1440 (each)	
Fort Calhoun	178	483	7/76
Ginna	210	595	11/76
Indian Point 2	264	482	12/75
LaCrosse	84	134	3/76
Maine Yankee	318	953	10/75
Millstone 1	880	2184	
Millstone 2	301	667	
Nine Mile Point 1	1140	1984	
Oconee 3	216	474	12/75
Oyster Creek	840	1800	3/77
Palisades	276	798	
Pilgrim 1	900	2500	
Point Beach 1 and 2	296	351	10/75
Prairie Island 1 and 2	198	687	
Quad Cities 1 and 2	1140 (each)	1460 (each)	
Rancho Seco	244	579	6/76
Robinson 2	236	272	2/76
Surry 1 and 2	464	1044	
Three Mile Island 1	174	496	
Trojan	280	651	
Turkey Point 3 and 4	217 (each)	621 (each)	3/77
Vermont Yankee	600	2000	
Yankee Rowe	172	391	12/76
Zion 1 and 2	340	868	8/76
[b]Midwest Fuel	100 MT	750	12/75
[c]NFS	260	320	
[d]Barnwell	400		
[d]Exxon	7000 (up to)		

---

[a] NFS is no longer accepting spent fuel.

[b] Storage capacity at fuel reprocessing facilities expressed in MT (metric tons). One MT is equivalent to about 2 PWR bundles or 5 BWR bundles.

[c] This list is informally maintained by the Office of Public Affairs, which does not attest to either its accuracy or completeness. Verification of the list may be obtained by a search of records available for public inspection and the agency's public document room, 1717 H Street, Washington, D.C.

[d] Initially capacity not yet authorized.

When spent fuel storage racks were first designed, the techniques used to calculate multiplication factors were not as precise as they are today, nor was pool storage space at a premium. Therefore, the racks were not built with any particular attempt to have a large storage capability. Thus, the fuel spacing in the initially installed racks was large enough to preclude any chance of criticality. As a result, calculated multiplication factors were low and stated variously as less than 0.7 or 0.9. These very conservative calculated multiplication factors were the licensee's option. The Commission reviewed the calculation of the multiplication factor, and found it conservative and acceptable.

We believe that a multiplication factor of 0.95 or less, when calculated with established techniques, is acceptable. We permit fixed poison material in be incorporated in rack design, but we do not give credit for soluble boric acid in the pool water. When fixed poison is used, we require in situ testing to verify that the poison has indeed been installed. A multiplication factor of less than 0.95 and the use of fixed poisons has reduced the centerline to centerline spacing of the fuel in racks for PWR assemblies from a previous value of about 21 inches to about 12 inches. In BWR's, the change in dimension is from about 10 inches to about 8 inches.

Another design consideration is pool and fuel cooling. Each pool is provided with a heat removal system that uses pumps and heat exchangers to transfer fuel decay heat energy to the ultimate heat sink; e.g., river or cooling pond. Adequate cooling capacity must be provided so that the pool water temperature is maintained low enough to prevent damage to the pool structure and excessive evaporation. A nominal temperature for normal operation of up to 150° F is acceptable. Since by far and away most of the total decay heat energy to be removed by the cooling system comes from the recently discharged fuel, storing more and older fuel in the pool does not greatly increase the required cooling capability. In addition to the heat removal system capability, we verify that the rack design permits adequate circulation of cooling water past the individual fuel assemblies. Heat is removed from the fuel assemblies by the natural convective flow of surrounding pool water.

We also look at the structural design. The material used in the racks must conform to Section III of the ASME Code and must be compatible with the existing pool materials. The construction classification of the pool and the racks within it must be seismic Category 1.

In addition to these design considerations the staff reviews potential accidents. One accident consideration that may be different than those previously evaluated is a construction accident; i.e., dropping a heavy object such as a new rack on spent fuel already in the pool. Licensees must develop procedures for pool modification that do not require heavy objects to pass over spent fuel. These proposed procedures are then reviewed by NRC.

Modification to spent fuel storage pools could be done in a straightforward manner if no spent fuel were stored in the pool. The pool could be drained, new racks installed and the pool refilled. Obviously, when spent fuel is already stored in the pool, the actual modification procedure could be more difficult. In addition to doing work under water the licensee may need to install a few new racks and then bootstrap the installation of additional new racks. By that, I mean, he puts down new racks, transfers fuel from old racks to the new ones, removes the old racks, and then puts more new racks in the positions that were previously occupied by the old ones.

We also reevaluate a cask drop accident. We review the proposal to make sure that with fuel in a closer array that a cask drop accident could not cause unacceptable consequences. We may preclude the use of a cask until the cask handling system is judged acceptable. We also have issued specifications that preclude movement of heavy objects, including a cask, over fuel.

The consequences of storing a larger quantity of spent fuel in a storage pool are considered. Radioactive materials could leak from stored failed fuel and cause an increase in radioactivity of the pool water and the atmosphere above it. However, experience has shown that the major release of radioactivity occurs when the fuel is at temperature, i.e., while in the reactor. As fuel cools in the pool the escape of radioactivity from the fuel pellets decreases and hence the radioactivity escaping from the fuel also is reduced. Furthermore after a few months, the gaseous radioactivity is negligible. Thus, even with a large quantity of stored fuel, the radiation at the surface of the water is only a few mR/hr.

Radioactive solids from the fuel surface or radioactive particulates are removed from the pool water by a pool water cleanup system, which consists of filters and demineralizers. The additional radioactive waste associated with filter media or resins is small.

The additional personnel exposure associated with having expanded spent fuel storage capacity is negligible. It has been estimated to be a few man-rem/year. The measured personnel exposure incurred by the modification has been low, in most cases from 1-2 man-rem. The highest exposure to date is about 20 man-rem.

Conclusion

In conclusion, I would like to say that licensees of nuclear reactors have recognized that some spent fuel storage pools were becoming filled and that they could no longer follow a course of action whereby fuel would be stored for a short time and subsequently reprocessed. They consequently are taking positive steps to permit continued reactor operation. The Nuclear Regulatory Commission is reviewing these steps to assure that the public health and safety are not endangered.

DISCUSSION

UNIDENTIFIED SPEAKER: You mentioned that a group of utilities, and in our discussions, about an external structure. Is that a secret as to proof?

MR. CARTER: No. Nine Mile Point site was one, the Fitzpatrick facility, and that was one of the main ones. There was another case where the Yankee Organization had considered it; they had considered a wide range of options and this just happened to be one of them.

UNIDENTIFIED SPEAKER: With the Atomic Energy Act the responsibility of the NRC regarding the health and safety matters of the entire nuclear fuel cycle, why is it that the NRC continues to consider health and safety only in segments of the nuclear fuel cycle rather than in total? This seems to me to have contributed to the problems that have arisen with the fuel cycle and do not have the fuel processing plants available and other such problems. It seems to me that this is all related to health and safety and finer fuel cycles, whoever it is, it is a storing or spent fuel element should be considered with regard to the health and safety.

MR. CARTER: If I can rephrase it as, why has the Commission not looked at the entire fuel cycle? Why are we looking at particular segments?

UNIDENTIFIED SPEAKER: Why have you looked at it only in segments rather than in total?

MR. CARTER: Recognizing that somebody with the same name as mine has recently indicated that fuel reprocessing shall be is held in abeyance, at least it is not going to be done right now, I would simply have to answer that the fuel cycle question is a complex one. It is being adddressed by various environmental considerations, and I do not know but that it is being considered. I am not privy to some of the ins and outs of the overall fuel cycle. We have a report "gizmo" which goes to the Commission and there have been many things related to it. I cannot answer your question specifically as to why not, other than I know many things are being done with the overall in mind.

UNIDENTIFIED SPEAKER: Is any serious thought currently going on in the matter of, say, central storage, regional storage, rather than a site-by-site basis?

MR. CARTER: One group of utilities has considered this. This is one of the options they had looked at. They have not made any submittal, that I am aware of, for our approval. I must add that I am with the licensing reactors. If there was a regional pool submittal that came in, I am not aware of it. I do not believe there is one. I indicated very quickly in my talk that the regulatory staff about 2 years ago prepared a guide to help anyone that wanted to get into regional storage. There are many problems that you have heard about. Some of them arose today; wondering if they can ship spent fuel across State lines. Licenses have to be a regional mainstay. There are not many States that have enough reactors to justify it as a possibility.

UNIDENTIFIED SPEAKER: I may have missed it when you were giving your presentation. In looking at all of the efficiencies that you can have existing, fuel and storage, and some of the plans you are aware of to perhaps build up some limited onsite separate storage pools, how far down the road is that decided assurance that nuclear plants will be able to operate and how does that relate to not optimistic but realistic projections as to terminal waste storage as per the ERDA program?

MR. CARTER: There is an ERDA report, ERDA 25, that was first put out about 2 years ago, and updated in 1976, and there is another update due out shortly. I have seen a working draft of the latest update of it in which they make projections of how many plants would be affected. The difficulty with all of their projections and assumptions is how many licensees make what requests for expansion? I personally have a belief that utilities are going to make an increase in the order of 100 percent on the pools when they have the capability to do so. Most have it. If you take that as presumption, and it is a big one, and you can shuffle fuel around, if that is an approved regulatory action which has not yet been taken, but it is under review right now, I personally do not see a problem until the end of the 1980's. I do not see a problem then necessarily if new reactors with large pools are being built.

I personally feel that there will be some plants impacted. There is one plant today that has made a submittal to NRC indicating that their basin is full now, that they are due for refueling this fall, or next spring, and that they are going to need some action to prevent a reduction of power. I think that a few plants will be impacted like this. I think there will need to be cooperation among the utilities to permit the away from reactor storage, such as the GE Morris, to be used for these people. I do not know that this cooperation will take place.

UNIDENTIFIED SPEAKER: I was particularly concerned as to especially some of the facilities there are where environmental concern is fairly active. And I was wondering how realistic is it when you look at past experience with environmental oppositions. I know that there are those that are going to try to make a mountain out of this situation.

MR. CARTER: Well, I can say right now there have been 30-some total applications. There have only been environmental intervention or contentions on four of them. One was resolved. There are only three contentions out of the 15 unresolved applications. The one utility that is impacted this year does not have any environmental contention on their application that I am aware of. Whether the others do, I do not know. Your guess is probably better than mine, being perhaps closer to the pulse. All we can do is review each future application and see what comes.

UNIDENTIFIED SPEAKER: I think we are one of the States that has intervened. We have one of the three cases, and I think the question the gentleman in the back asked, is a very important one. Why don't you look at the whole fuel cycle in terms of public health? What you are trying to do is State intervention. The State procedure allows only certain things to happen and we find that we cannot look at the transportation of spent fuel--let's say is part of the fuel cycle--and what impact it really would have and what implications an accident might have.

UNIDENTIFIED SPEAKER: Assuming that you got to the mid-1980's--that would be about 7 years away; would you stop to construct a centralized storage pool and go through the applications and so forth? It would be difficult if someone submitted an application today to make the mid-1980's inoperable. If your branch is also looking at one of the other alternatives, and that is retrievable storage other than a pool of water, recognizing the reprocessing delayed indefinitely, I have seen where they would put these in small casks with something like lead or aluminum.

MR. CARTER: The group that I am with is not looking at that particular aspect. People are looking at the capability or the acceptability of storing fuel not necessarily in casks, but possibly even storing fuel in air. The heat decay rate is low enough that this may be possible.

USE OF RADIATION IN BENIGN DISEASES

Albert W. Hilberg, M.D.

Division of Medical Sciences
National Research Council
National Academy of Sciences

What will be reported in this presentation is essentially a preview of a rather sizeable document prepared by a Committee to Review the Use of Ionizing Radiation for the Treatment of Benign Diseases. This Committee of the Division of Medical Sciences, Assembly of Life Sciences, National Research Council, National Academy of Sciences, has conducted its study under a contract with the Bureau of Radiological Health, FDA, HEW. The Committee was chaired by Dr. Raymond Seltser (Professor of Epidemiology at Johns Hopkins School of Hygiene and Public Health, Baltimore, Maryland), and its membership included epidemiologists, dermatologists, radiotherapists, internists, surgeons, pathologists, pediatricians radiobiologists, radiation physicists, and ophthalmologists.

The final report of the Committee is expected to be delivered to the Bureau of Radiological Health within the next several weeks.

While what is contained in today's presentation will very likely be a part of the final report, there may still be some changes in emphasis and in final disposition of some issues.

Over the past several decades, ionizing radiation has been used for the treatment of a variety of diseases, both malignant and benign. The use of ionizing radiation in the treatment of benign diseases was particularly common in the treatment of benign skin diseases and various other benign conditions. These include hyperplasia of the tonsils and adenoids, mastoiditis and sinusitis, middle ear infection, cervical adenitis, presumed enlargement of the thymus gland, hemangiomas, keloids of the head and neck, tinea capitis, and acne. Studies pointing to the likelihood that such exposed individuals are at higher risk than expected for the development of tumors of the head and neck region has raised legitimate concerns in the minds of both the medical profession and the public (1-8).

The use of ionizing radiation as a mode of therapy, particularly for benign diseases, has been subjected to close examination in recent years with the result that radiation therapy as a treatment of choice has been discontinued in many instances. However, ionizing radiation continues to be the treatment of choice in some benign diseases that do not respond to other modes of therapy. It is also the treatment of choice in the unusual instance of a life-threatening benign disease that cannot be surgically or medically managed.

A review of the present use of ionizing radiation for the treatment of benign diseases clearly demonstrates a decline in its use as well as a continual reappraisal by medical specialists of the appropriate need for radiation therapy. However, the review also indicates that ionizing radiation continues to be used by certain specialists for the treatment of categories of benign disease even though substantial disagreement exists concerning the necessity of such therapy.

In a recent survey conducted by Dr. Herbert Goldschmidt, including dermatologists in both the United States and Canada, he found that 55.7 percent of the dermatologists are not using radiation therapy at all. Forty-four and three-tenths percent use superficial x-ray therapy and/or Grenz-ray therapy at least once a week.

The more frequent indications for superficial x-ray treatment by dermatologists surveyed are basal cell carcinoma, 89.1 percent; Squamous cell carcinoma, 79.8 percent; and mycosis fungoides, 78.5 percent. The benign diseases treated included lymphacytoma, 55.8 percent; keloids, 55.5 percent; and acne, 41.8 percent. Also Grenz-ray therapy available in about 25 percent of dermatologists offices is used for eczematous skin disease (44.5%), pruritus ani and vulvae (35%), lichen simplex (30.4%), and psoriasis (30.1%).

Dr. Goldschmidt states that the results of the survey emphasize that the major indications for x-ray therapy are in the management of malignant skin tumors. Most of the dermatologists surveyed limit use of ionizing radiation for benign skin disorders to cases where other forms of treatment were found to be ineffective, or the use of radiation is adjunctive to other forms of therapy (9).

In a survey conducted for this (NAS) study by one of the radiotherapists on our Committee, it was determined that in 17 of 19 academic centers queried, the radiation therapy department did treat benign diseases. In two centers they did not. The experience reported in a survey of nonacademic radiation therapy departments was almost identical. The kinds of benign diseases most often treated in radiation therapy departments are keloids, hemangiomas, peptic ulcers, bursitis, parotitis, peyronies disease, and gynecomastia.

The ionizing radiation still used in present day therapy of benign diseases often has such physical characteristics and is subject to selection of radiation quality, quantity, and localization in such a manner as to avoid some of the hazards associated with more penetrating and damaging radiation. Nevertheless, if the available information concerning low-level exposure effects, including a linear hypothesis of effects, is considered, then any amount of ionizing radiation may be regarded as a potential risk to an exposed individual.

There are several reviews of the predicted risks to human beings exposed to low levels of ionizing radiations (10). Although there is an honest difference of opinion, most estimates of cancer risk are based on some form of linear extrapolation of effects from those seen at much higher exposure to radiation. However, in spite of the difference, most investigators recognize that cellular effects, as well as tissue effects, from exposure to very low levels of radiation, do occur and could possibly lead to permanent deleterious biological effects.

It may be useful to summarize the type of evidence concerning radiation effects observed in populations treated for a variety of benign conditions in the past:

1. X-ray therapy for ankylosing spondylitis. The British studies of 14,554 patients treated with therapeutic doses of x rays ranging from approximately 375 to more than 2,750 rads (mean final dose) per patient resulted in an estimated increase in leukemia from 5.4 expected cases to 60 observed (11).

2. An excess in leukemia has been found in several studies of female patients exposed to radiation for castration for the relief of certain benign gynecological conditions (12-15). There was also an increase in overall cancer mortality in one study following radiation for castration (16).

3. Leukemia excess has been reported in followup studies of children treated by x-ray for thymic enlargement (17) and in another group of children treated by x-ray for tinea capitis (18).

4. Although the data concerning the induction of thyroid cancer following I-131 therapy in hyperthyroid patients is not clear cut, there is indication that 5 to 10 years after treatment of hyperthyroidism with I-131 there results over a 50 percent incidence of hypothyroidism suggesting that extensive death of thyroid cells is the result of this treatment (19). There is also evidence that there are large numbers of chromosomal aberrations (up to 33 percent) in cells cultured from patients who received 400 to 700 rads of x rays to the thyroid gland in infancy 31 to 37 years previously (20). Thyroid disease will be discussed in detail by Dr. Sloan.

5. There have been a few dozen instances of bone tumors developing at the site of previous therapeutic external irradiation, including a group receiving radiotherapy to the mediastinum in infancy (20,21). Bone tumors have also been reported in spondylitis patients given x-ray therapy to the spine--with 4 cases observed where only 0.6 case was expected (11). Another group of subjects includes approximately 900 patients given radium for therapy of bone tuberculosis or ankylosing spondylitis in Germany within the last two decades (22). There has been a sizable number of bone sarcomas developing in this group of patients.

6. The incidence of skin cancer is increased following intensive irradiation of the skin, especially in the presence of chronic radiodermatitis (23,24). The data concerning malignancies in patients receiving superficial radiation therapy for both benign and malignant conditions is somewhat conflicting. Sulzberger's studies show no difference between irradiated and nonirradiated populations with doses up to 1,000 R of superficial radiation (25). On the other hand, Takahashi studied 308 cases of skin cancer and found that 14, or 4.5 percent, had received radiotherapy of the primary site whereas only 6, or 0.79 percent, of the control group had been so exposed (26). Martin reported a relative risk of 3.74 in over 600 irradiated patients who had received 7,000 R or more in some instances (27).

A number of reports suggest the likelihood that basal cell cancers have been induced in patients treated for ankylosing spondylitis (11) and rheumatoid arthritis (28); and in children subjected to x-ray epilation for tinea capitis (ringworm of the scalp) (29).

A significantly increased rate of breast cancer has been reported in women given localized x-ray treatments for acute post-partum mastitis (30). In a series of 606 women, 13 cases were reported as compared with 5.9 expected from New York State incidence figures.

An approximately two-fold increase in the relative risk of lung cancer was observed in the study of patients with ankylosing spondylitis treated with x-ray therapy (11). In these cases, large doses of x rays were delivered to the spine and doses to the bronchial epithelium were estimated to average about 400 rads. In addition, analysis of the data from these patients treated with x rays for ankylosing spondylitis shows a significant excess of stomach cancers occuring 6 to 27 years after irradiation (11). These patients treated with fractionated x-ray exposures for ankylosing spondylitis also showed an excess mortality for cancers of all sites during the 27 years immediately following irradiation.

In any consideration of effects of radiation exposure, one becomes acutely aware of the potential overreaction to the concept of the risks inherent in radiation therapy--particularly in those instances where one might be trading off a known risk of radiation against the unknown risk of some other therapeutic modality. Therefore, the concept is strongly endorsed that it must remain the prerogative of the physician to have available for use any form of therapy--radiation, drug, or others--in which the benefits accruing to the patient from its use are considered to outweigh the risks inherent in its use.

As a result of the deliberations of the Committee, several conclusions were drawn which allow for some general statements and recommendations:

I. The potential risk of treatment with any form of ionizing radiation of a benign, non-life threatening, disease must be recognized. Ionizing radiation therapy may be considered if other conventional, safer, and accepted methods of therapy have not succeeded in alleviating the condition and the potential consequences of no further treatment are unacceptable.

II. The potential long-term risk of radiation therapy should be considered before therapy is instituted. This should take into account the quality of radiation, total dose, overall time over which radiation is administered, underlying organs at risk, and shielding factors.

III. Infants and children should be treated with ionizing radiation only in very exceptional cases after careful evaluation of the potential risk compared with the expected benefit.

IV. Direct irradiation of the skin areas overlying organs that are particularly prone to late effects (e.g., thyroid, eye, gonads, and breast) should be avoided.

V. The survey conducted by the Committee indicates that, as the use of radiation for the treatment of benign disease has decreased, the opportunities for adequate training in the techniques of radiation therapy and radiation proection are also diminishing outside of the specialty of radiology. Medical practitioners using ionizing radiation for the treatment of benign disease should be adequately trained in both the practical as well as the theoretical aspects of radiation therapy and protection.

VI. Meticulous radiation protection techniques should be used in all instances. These include lead shielding of organs that might be affected. The use of cones and lead shields is strongly recommended in order to reduce scatter radiation. Not only the medical practitioner but also all paramedical and technical assistants should be trained and knowledgeable concerning radiation protection techniques.

VII. Since the less penetrating x-ray qualities, for example Grenz rays, offer a wider margin of safety, wherever possible the depth of the penetration of the x-ray beam should be chosen in accordance with the depth of the pathological process.

VIII. Laboratory and epidemiologic studies should be initiated and/or continued by appropriate agencies and investigative groups to fill the obvious gaps in our knowledge of the nature of the effects of ionizing radiation in the doses used in the past--and currently--in the treatment of benign diseases. One need is the elaboration of the actual doses to various target organs. A second need is the followup of appropriate groups of individuals exposed to benign disease therapy in the past, those who may have had such exposure to the thyroid, breast, and other specific target organs.

In closing I would like to again quote, as I did earlier this week, from a publication of the Bureau of Radiological Health dated October 1976:

> "Valuable therapeutic and diagnostic x-ray techniques which are of great benefit to patients cannot be abandoned because of the risk of delayed harmful effects; on the other hand, if the same diagnostic information or therapeutic results can be obtained using techniques which reduce radiation exposure to the patient, or if equally effective non-radiologic procedures which do not involve such risks are available, such methods should be used" (31).

REFERENCES

1. Duffy, Jr., B.J. and Fitzgerald, P.J.: "Cancer of the Thyroid in Children: A Report of 28 Cases." Cancer 3:1018-1032, 1950.

2. Clark, D.E.: "Association of Irradiation with Cancer of the Thyroid in Children and Adolescents." JAMA 159: 1007-1009, 1955.

3. Simpson, C.L., Hempelmann, L.M. and Fuller, L.M.: "Neoplasia in Children Treated with X-rays in Infancy for Thymic Enlargement." Radiology 64: 840-845, 1955.

4. Saenger, E.L., Silverman, F.N., Sterling, T.D. etal: "Neoplasia Following Therapeutic Irradiation for Benign Conditions in Childhood." Radiology 74: 889-904, June, 1960.

5. DeGroot, L. and Paloyan, E.: "Thyroid Carcinomas and Radiation. A Chicago Endemic." JAMA 225: 487-491, 1973.

6. Refetoff, S., Harrison, J., Karanfilski, B.T., Kaplan, E.L., DeGroot, L.G. and Bekerman, C.: "Continuing Occurrence of Thyroid Carcinoma After Irradiation to the Neck in Infancy and Childhood." NEJM 292: 171-175, Jan. 23, 1975.

7. Farus, J.F., Schneider, A.B., Stachura, M.E., Arnold, J.E., Ryo, U.Y., Pinsky, S.M., Colman, M., Arnold, M.J., and Frohman, L.A.: "Thyroid Malignancy Occurring as Late Consequence of Head and Neck Irradiation: Evaluation of 1056 Patients." NEJM 294: 1019-1025, May 6, 1976.

8. Hemplemann, L.H., Hall, W.J., Phillips, M., Cooper, R.A. and Ames, W.R.: "Neoplasms in Persons Treated with X-rays in Infancy: Fourth Survey in 20 Years." JNCI 50: 519-530, No. 3, September, 1975.

9. Goldschmidt, Herbert: "Ionizing Radiation Therapy in Dermatology." Arch. Derm., Vol. III, 1511-1517, November 1975.

10. National Academy of Sciences - National Research Council. "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation." Report of the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR). U.S. Government Printing Office, Wash., D.C., 1972.

11. Court-Brown, W.M. and Doll, R., "Mortality from Cancer and Other Causes After Radiotherapy for Ankylosing Spondylitis." Brit. Med. J. 5474: 1327-1332, 1965.

12. Doll, R. and Smith, P.G., "The Long-Term Effects of X-Irradiation in Patients Treated for Metropathia Haemorrhagica." Brit. J. Radiol. 41:362-368, 1968.

13. Brinkley, D. and Haybittle, J.L., "The Late Effects of Treatment of Artificial Menopause by X-Irradiation." Brit. J. Radiol. 42:519-521, 1969.

14. Alderson, M.R. and Jackson, S.M.,: "Long-Term Follow-up of Patients with Menorrhagia Treated By Irradiation." Brit. J. Radiol. 44: 295-298, 1971.

15. Randall, C.L., Paloucek, R.P., Graham, J.R. and Graham, S.: "Causes of Death in Cases of Preclimacteric Menorrhagia." Am. J. Obst. Gyn. 88: 880-887, 1964.

16. Waggoner, J.K.: "Leukemia and Other Malignancies Following Radiation Therapy for Benign Gynecological Disorders." Paper presented at American Public Health Association Annual Meeting, Nov. 12, 1969.

17. Hempelmann, L.H., Pifer, J.W., Burke, G.J., et al: "Neoplasms in Persons Treated with X-rays in Infancy for Thymic Enlargement. A Report of the Third Follow-up Survey." J.Nat.Can.Inst. 38: 317-341, 1967.

18. Albert E.R. and Omran, A.R.: "Follow-up study of Patients Treated by X-ray Epilation for Tinea Capitis." Arch.Environ.Health 17: 899-950, 1968.

19. Green, M. and Wilson, G.M.: "Thyrotoxicosis Treated by Surgery or Iodine-131, With Special References to Development of Hyperthyroidism." Brit. Med. J. 1:1005-1010, 1964.

20. Doida, Y., Hoke, C. and Hempelmann, L.H.: "Damage in Thyroid Cells of Adults Irradiated with X-rays in Infancy." Rad. Res. 45: 645, 1971.

21. Bloch, C.: "Postradiation Osteogenic Sarcoma. Report of a Case and Review of Literature." Am.J.Roentgenol. 87: 1157-1162, 1962.

22. Speiss, H., and Mays, C.W.: "Bone Cancers Induced by 224 Ra (THX) in Children and Adults." Health Physics 19: 713-729, 1970.

23. Traenkle, H.L.: "X-ray Induced Skin Cancers in Man." National Cancer Institute Monograph: Biology of Cutaneous Cancer. 10:423-432, 1963.

24. Cipollaro, A.C. and Crossland, P.M.: "X-rays and Radium in the Treatments of Diseases of the Skin." 5th Ed. Lea and Febiger, Philadelphia, pp. 391-398, 1967.

25. Sulzberger, M.B., Baer, R.L., and Barota A.: "Do Roentgen Ray Treatments as Given by Skin Specialists Produce Cancers or Other Sequelae?" Arch. Dermat. and Syph. 65:639-655, 1952.

26. Pifer, J.W., Toyooka, E.T., Murray, R.N., Ames, W.R. and Hempelmann, L.H.: "Neoplasms in Children Treated with X-rays for Thymic Enlargement, 1. Neoplasms and Mortality." J.Nat.Cancer Inst. 31: 1333-1356, 1963.

27. Martin, H., Strong, E., and Spiro, R.H.: "Radiation Induced Skin Cancer of the Head and Neck." Cancer 25:61-70, 1970.

28. Sarkany, I., Fountain, R.B., Evans, C.D., Morrison, R., and Star, L.: "Multiple Basal-cell Epitheliomata Following Radiotherapy of the Spine." Brit. J. Dermatol. 80:90-96, 1968.

29. Shore, R.E., Albert, R.E., Pasternack, B.S.: "Follow-up Study of Patients Treated by X-ray Epilation for Tinea Capitis. IV Resurvey of Post-Treatment Illness and Mortality." Arch. Environ. Hlth. 31:21-28, 1976.

30. Mettler, F.A., Hempelmann, L.H., Dutton, A.M., Pifer, J.W., Toyooka, E.T., and Ames W.R.: "Breast Neoplasms in Women Treated with X-rays for Acute Postpartum Mastitis. A Pilot Study." J.Nat.Can.Inst. 43:803-811, 1969.

31. Barnett, Mark H., "The Biological Effects of Ionizing Radiation: an Overview," HEW Publication (FDA) 77-8004, October, 1976.

BIBLIOGRAPHY

1. Iknayan, H.F., "Carcinoma Associated with Irradiation of the Immature Breast." Radiology 114: 431-433 (Feb. 1975).

2. Modan, B., Mart, H., Baiditz, D., Steinitz, R., and Levin, S.G., "Radiation Induced Head and Neck Tumors." Lancet 1: 277-279, 1974.

3. Takahashi, S.: "A Statistical Study on Human Cancer Induced by Medical Irradiation." Acta Radiologica 23: 1510-1530, 1964 (Nippon Acta Radiologica).

THYROID IRRADIATION FOLLOWUP STUDIES

Margaret H. Sloan, M.D.
National Cancer Institute

During the past 4 years numerous articles and conferences in the United States have been concerned with the problem of irradiation-related thyroid cancer appearing many years after treatment with x-irradiation or radium for a wide variety of non-malignant conditions of the head, neck, and upper thorax. Such treatments were given during a period of approximately 30 years between the mid-twenties and the mid-fifties. A partial listing of the conditions for which such irradiation was given is shown in table 1.

Radiation treatments for these conditions were for the most part remarkably effective and were considered good medical practice at the time. They were used with great enthusiasm over that 30-year period, although irradiation for infections began to be abandoned with the advent of antibiotics in the 1940's.

The first report suggesting a linkage of such irradiation with the subsequent development of thyroid cancer was that of Duffy and Fitzgerald in 1950 (1) at Memorial Hospital, New York. These investigators found that of 28 patients under the age of 18 years who were operated on for thyroid cancer in the period 1932-1948, nine had a history of irradiation of the thymus gland in infancy.

This report was soon confirmed by others (2,3) and, although there were some investigators who did not agree with these findings at first (4), the reality of such a relationship was well accepted by 1960 (5).

The use of ionizing radiation for most of these conditions was, therefore, discontinued by 1960. However, as indicated in the report on "The Use of Ionizing Radiation in the Treatment of Benign Diseases" prepared by the National Academy of Science (6), over 40 percent of the dermatologists in the United States are still using x-ray therapy for the treatment of acne and of some hemangiomas of the face and neck.

The magnitude of the problem posed by irradiation-related thyroid cancer is difficult to determine. How many people actually received irradiation to the head and neck during that 30-year period is a matter of conjecture. The majority of the patients were irradiated in the private offices of radiologists and dermatologists and their records were not entered into any continuing system. Even for those who were irradiated in the departments of radiology in hospitals which are still in operation today, records are often no longer available from such a remote period and, if they are, are rarely in a condition permitting ready retrieval.

The problems encountered in actually tracing these individuals are enormous and the process is very expensive. Many have moved. Most of the women have changed their names through marriage. Their parents and childhood physicians are often no longer available or are unable to recall such treatments and the patient himself was usually too young to remember. In one recall program (7), a most intensive tracing effort, directed at 1,000 patients for whom good records were available, only succeeded in bringing in one-fourth for examination, and at a cost for tracing alone of $35 to $40 per individual, or about $150 per patient seen.

The practice of such irradiation varied greatly from radiologist to radiologist and from city to city. Best estimates are that about 75,000 were exposed in the Chicago area, 70,000 in Detroit, 39,000 in Pittsburgh, and so forth. In other cities the number was very small. We estimate the total at somewhere between one and four million, but we shall probably never know exactly.

Has this introduction of radiation exposure in the population been reflected in any detectable increase in the national incidence of thyroid cancer in recent years? It appears that it may have been. Figure 1 shows the change in age-adjusted incidence rates for white females and white males between the Second National Cancer Survey in 1947 (8) and the Third National Cancer Survey in 1961-71 (9). The age-adjusted incidence rates increased from 1.2 to 2.4/100,000 for white males and from 3.8 to 5.7/100,000 for white females during that 23-year period (10). The numbers of blacks in the 1947 survey was not sufficient for accurate calculation; therefore, this graph shows data only for the white population. The increase was particularly marked in the age group which was 26-35 at the time of the Third National Cancer Survey. In this group, the incidence rate was up to four times that in 1947. Some of these individuals could possibly have been irradiated as infants or children between 1935 and 1945. It is of interest that the mortality rates have gone down slightly in spite of the increase in incidence (Fig. 1). This presumably reflects improved clinical management and possibly earlier detection.

In the 1950's and 1960's, interest centered on the individuals who had received irradiation to the thymus in infancy and it was really not recognized until the early 1970's that people who received irradiation for other conditions noted in table 1, particularly those treated for enlarged tonsils and adenoids, were constituting an increasing percentage of the adults with thyroid tumors.

Table 2 shows the most important studies which have led to our present understanding of the situation. The oldest study in this table is that of Hempelmann, who, 2 years after the 1950 report of Duffy and Fitzgerald (1), began a retrospective and prospective study of 2,872 individuals who received irradiation to the thymus in infancy. These were carefully matched with over 5,000 sibling controls and have been followed at intervals (11-15) into the present decade. Hempelmann's most recent report in 1975 (16) updated this series to 1971 by which time 24 thyroid cancers had been found in the exposed population for an incidence of 0.8 percent, whereas none had been found in the controls. In a subgroup which received a higher dose of radiation, the incidence was by then 5 percent. At least four additional thyroid cancers have appeared in this group since 1971. This represents a very significant increase compared to the incidence in the general population in 1970 of 0.0037 percent.

Another group of reports of thyroid cancer related to irradiation concerned the atomic bomb survivors in Japan who received whole body irradiation (both direct and from fallout) in Hiroshima and Nagasaki in 1945. These have been followed closely by the Atomic Bomb Casualty Commission (ABCC) under the administration of the National Academy of Sciences (NAS) and the support of the Energy Research and Development Administration (ERDA) and the National Cancer Institute (NCI) (the ABCC was recently reorganized with Japanese Government support as the Radiation Effects Research Foundation). The first report of thyroid tumors in this population was by Hollingsworth, et al., in 1963 (17). The most recent report was by Parker et al., in 1974 (18), which updated the figures to 1971. By that time in 20,000 individuals entered into the Adult Health Study who received doses to the thyroid ranging from less than 50 to more than 200 rads, 40 cases of thyroid cancer had been diagnosed clinically and another 34 cases diagnosed histologically at surgery or autopsy. This gives an incidence of clinically diagnosed disease of 0.2 percent. Latent periods ranged from 3 to 29 years and new cases are still occurring.

A similar group of patients irradiated accidentally in the Marshall Islands, as a result of a test bomb explosion in 1954, has been followed by a team of scientists led by Robert Conard at Brookhaven National Laboratory. Their first report on thyroid tumors was in 1966 (19) and their most recent one was in 1976 (20). By that time they had found thyroid tumors in 42 (15 percent) of the 280 individuals exposed, of which 7 or 2.5 percent of the total number were found to have thyroid cancer on surgery after latent periods of from 9 to 20 years. However, of a group of 19 children who were under 10 years old at the time of the exposure on Rongelap, the island receiving the heaviest exposure, all 19 have developed thyroid abnormalities. Seventeen had tumors of which one proved to be malignant, and two developed atrophy of the gland. This entire population continues to be at increased risk 23 years after exposure. Two

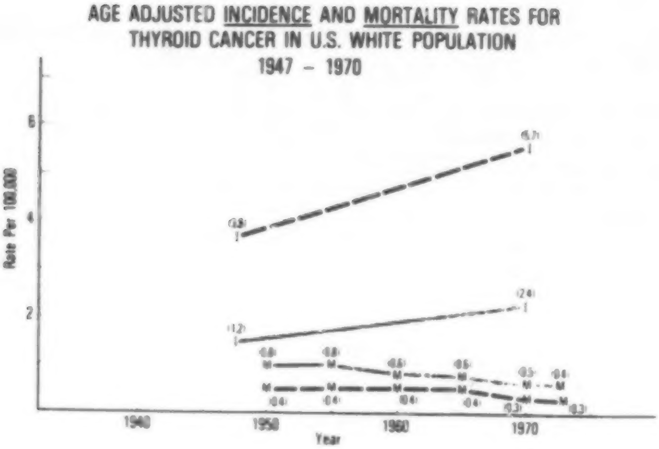


Figure 1

Table 1

CONDITIONS FOR WHICH IRRADIATION WAS GIVEN TO HEAD, NECK AND UPPER THORAX WHICH INVOLVED THE THYROID GLAND
1920 - 1955

Enlarged Thymus

Enlargement and Inflammation of Tonsils and Adenoids

Deafness Due to Hypertrophy of Lymphoid Tissue Around Eustachian Tubes

Tinea Capitis

Cervical Adenitis

Tuberculosis of Cervical Nodes

Asthma

Whooping Cough

* Hemangiomas of Head and Neck

* Acne

Other Types of Dermatitis

Acute Postpartum Mastitis

I^{131} Administration for Treatment of Thyrotoxicosis

* X-Ray Therapy for Non-Thyroid Malignancies in Head and Neck Region

* Still being given today

Table 2

THYROID LESIONS AFTER RADIATION

Area Treated	Estimated Dose to Thyroid (Rads)	Incidence (%)		Latent Period	Source
		Total with Thyroid Nodules	Cancer		
Scalp	6.2 - 7.4 6.8	8 0.51	0.11 0	4 - 21 yrs 4 - 29 yrs	Modan et al 1977 Shore, Albert et al 1976
Thymus					
Total Group	119	1.8	0.8	5 - 40 yrs	Hempelmann et al 1975
Subgroup	399	7.6	5.0		
Tonsils, adenoids and nasopharynx plus	100 - 1500	26.2	6.8	24.9 ± 4.2 yrs	Refetoff, DeGroot et al 1975
some other head, neck and thorax	807	27.3	5.7 - 9.0	28.5 ± 1.0 yrs	Favus, Frohman et al 1976
Radiation Fallout (Marshall Islands)	69 - 175 700 - 1400	7.0 - 39.0	0 - 6.3	9 - 23 yrs	Conard, Dobyns et al In press
Subgroups					
Children <10 yrs	175	89.5	5.3		
10 - 18 yrs		25.0	8.3		
>18 yrs		15.2	6.1		
^{131}Iodine Therapy	>10,000	0.17	0.08	5 - 10 yrs	Dobyns et al 1974

additional cases of thyroid cancer have been diagnosed this year from the island receiving the lowest dose of radiation.

Two groups have reported on the long term results of irradiation of the scalp for tinea capitis. Albert's first reports appeared in 1968 (21,22) and were updated in 1976 (23). Modan reported on a much larger series in 1974 (24). Both showed that doses to the thyroid as low as 6-9 rads could also produce tumors of the thyroid gland after intervals of 4-29 years. In Albert's series, there have been six thyroid adenomas in 2,215 patients treated, compared to none in a matched control group. In Modan's series, there have been 12 thyroid carcinomas so far in 11,000 subjects compared to three in over 16,000 controls, or a rate of 0.11 percent in the study group versus 0.02 in the controls. It is of interest that, to date, all the tumors reported in Modan's series have been malignant and all in Albert's much smaller series have been benign. The dose level in Albert's series was just slightly below Modan's. Both were carefully checked by the Bureau of Radiological Health using phantoms.

Thousands of individuals with Graves' disease have been treated with radioactive iodine (^{131}I) in the United States over the past 20 years. Because the thyroid selectively concentrates iodine, radiation doses of 10,000 rads or more have been absorbed by the gland. Cases of thyroid cancer have been diagnosed in such patients after intervals of from 5 to more than 19 years. However, there is great uncertainty as to how many of these cases were induced by radiation and how many reflected the underlying abnormalities of the gland. The Cooperative Thyrotoxicosis Followup Study, involving over 30,000 individuals with Graves' disease in 26 different institutions, was designed to compare the results of treatment by surgery alone, ^{131}I, and antithyroid drugs. Unfortunately, it was terminated in 1968 before an adequate followup period had elapsed. At the time of termination, it appeared that there were almost twice as many carcinomas appearing in patients treated with ^{131}I as with surgery alone (25).

The papers which really precipitated the intense interest in this subject in recent years included one by DeGroot and Paloyan in 1973 entitled "Thyroid Cancer. A Chicago Endemic" (26). These investigators reported that 40 percent of patients operated on for thyroid cancer at the University of Chicago Hospital between 1968 and 1972 had a history of prior radiation to the head, neck, or upper thorax in infancy, childhood, or adolescence for the variety of conditions previously mentioned, a large number of them for enlarged tonsils and adenoids. They then examined 100 asymptomatic individuals, all of whom had a history of such radiation, and found that 26 percent had palpable thyroid tumors. Only 15 were operated on, but of those, eight were found to have benign tumors and seven were found to have cancer giving an apparent incidence of cancer of 7 percent.

Meanwhile, Frohman's group at Michael Reese Hospital in Chicago had located a file of 5,266 patients who had received x-radiation or radium treatments to the head and neck in infancy or childhood at that hospital and had launched an energetic recall program. In approximately 1,500 individuals examined to date (7), they have found thyroid tumors in 27 percent. Of those undergoing surgery, one-third have been found to have cancer for a projected total incidence of 9 percent.

So far no one has encountered a higher rate than those reported in the two studies in Chicago, but new cases are still appearing and what the incidence will be over the entire lifetimes of these individuals remains to be seen.

Thus, we are confronted by a large cohort of people in the United States, most of whom received x-radiation to the head, neck, or upper thorax during the 30-year period 1925-55. Some additional subjects have been added later through the continued but decreasing use of radiation by some dermatologists in the treatment of acne. We know that it is important that these people be examined, but how can we reach them?

Activities of the Division of Cancer Control and Rehabilitation, National Cancer Institute

This unique population at increased risk of developing thyroid cancer was of obvious concern to the Division of Cancer Control and Rehabilitation (DCCR) of the National Cancer Institute (NCI). The subject was given careful consideration by the Division in early 1975, and it was decided to bring together the leading experts in the field to obtain their best advice as to the most appropriate course for the NCI to pursue. The DCCR accordingly organized a workshop on "Late Effects of Irradiation to the Head and Neck in Infancy and Childhood" with the cooperation of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) and the Bureau of Radiological Health (BRH). The workshop was held in Bethesda, Maryland, September 24-25, 1975. A summary of that meeting was published in Ca - A Cancer Journal for Clinicians (28).

The consensus of the experts participating in that workshop can be expressed in three major recommendations for application at the national level as follows:

1. That all hospitals which have suitable records of individuals receiving therapeutic irradiation to the head, neck, or upper thorax for non-malignant conditions in the past, should endeavor to carry out recall programs, to contact these individuals and encourage each of them to have a careful examination of the thyroid gland.

2. That practicing physicians be provided with educational materials presenting the best current information about radiation-related thryoid cancer and about measures for detection, diagnosis, treatment, and followup.

3. That after physicians had been fully alerted to the problem and provided with the best guidance available, all appropriate communication channels should be used to reach the public with information about radiation-related thyroid cancer and with the message that all those with a known history of radiation treatments to the head, neck, or upper thorax should have a careful examination by a physician. Individuals should also be urged to consult with available parents or childhood physicians to determine whether they have been exposed.

In considering its response to these recommendations, the DCCR, in consultation with its advisors, reached the conclusion that a national recall program supported by the Federal Government would be neither feasible nor appropriate and that the cost would be prohibitive. It was also agreed that the examination of previously irradiated individuals by physicians should be considered a part of routine medical care and, therefore, could not be supported by the NCI. Finally, it was recognized that excellent demonstrations of ways and means to launch a hospital-based recall program when adequate records are available had already been carried out and that others were in progress. Therefore, it was concluded that there was no need for the Division of Cancer Control and Rehabilitation to support demonstration programs on this subject.

The Division has prepared the summary of the 1975 workshop under the title "Information for Physicians: Irradiation Related Thyroid Cancer" (20) as part of an NCI Pamphlet Series. This has been reprinted in whole or in part in many State and national medical journals and has been widely distributed as an NCI publication.

Public information documents have also been produced on the basis of the 1975 workshop and are now being disseminated through many channels by the Office of Cancer Communications and by the Division of Cancer Control and Rehabilitation of the National Cancer Institute.

Assistance in dissemination of the informational materials for both health professionals and the public has been provided by the Comprehensive Cancer Centers and their Cancer Information Services and these materials have been used as the basis for educational programs in their regions. Valuable help has also come from the American Cancer Society, which has distributed the materials through their divisions and chapters.

A larger conference on Radiation-Associated Thyroid Cancer was held in 1976 in Chicago under the joint support of the National Cancer Institute and the National Institute of Arthritis, Metabolism, and Digestive Diseases. The proceedings of that conference have been edited by DeGroot, et al. and published (30).

The Journal of the American Medical Association published summaries of both conferences in its issue of November 29, 1976 and many State medical societies have used these materials in educational programs for their members.

The American Hospital Association, at our request, is currently canvassing its membership to determine how many hospitals have undertaken recall, screening, or information programs on this subject. This inquiry in itself has stimulated many hospitals to consider or to start recall programs.

Dr. Brown Dobyns of Cleveland, with encouragement from the National Cancer Institute, has taken a different approach and is canvassing his colleagues among the Society of Head and Neck Surgeons and the American Thyroid Association to see how many of their patients coming to surgery for suspected thyroid cancer actually have a history of therapeutic irradiation to the head or neck and what were the reasons for the radiation treatment.

He and some other head and neck surgeons have a strong impression that the percentage presenting with a history of irradiation for acne is increasing. This may well be true. If the latent period for thyroid cancer is related to the age at irradiation, a longer latent period might be expected for individuals irradiated for acne as adolescents or young adults as compared with those irradiated for enlarged thymus or tonsils as infants or young children. The time for expression of a neoplasm may now have been reached for a significant number of acne patients.

Since x-radiation treatment for acne is still considered justifiable when the condition will not respond to any other form of therapy, we cannot expect to see the end of this problem for many years.

Meanwhile, the followup of the defined irradiated groups mentioned earlier is continuing under the support of ERDA, BRH, and the NCI. The NIAMDD is supporting basic and clinical research on thyroid disease and hopes to develop better methods for the prevention, early detection and diagnosis of thyroid abnormalities, including cancer. The Division of Cancer Treatment, NCI is supporting studies to develop better methods of treatment. Our Division and the Office of Cancer Communications will continue to place maximum emphasis on education of health professionals and the public.

One of our distribution targets has been the State and Territorial Health Officers and we have assumed that we would reach the Radiation Control Program Directors through them. I hope we were correct and that you found the materials useful. We believe that we have gone about as for as we can go from the platform of the National Cancer Institute and trust that you will be interested in aiding at the State level in the ongoing education effort about radiation-related thyroid cancer.

It is our hope that, together, we can deal effectively with this iatrogenic disease which has arisen from actions taken many years ago. It must be emphasized that the physicians who gave those radiation treatments were convinced that they were providing their patients the very best and most up-to-date treatment available. We must cope with the after effects of those treatments in a manner which will be in the best interest of the people at risk.

REFERENCES

1. Duffy, B.J., Jr. and Fitzgerald, P.J. Cancer of the thyroid in children: a report of twenty-eight cases. Journal of Clinical Endocrinology and Metab 10:1296-1308 (October 1950).

2. Winship, T. Symposium on thyroid tumors: carcinoma of the thyroid in children. Tr Am Goiter Assoc (1951):364-389 (1952).

3. Winship, T. and Chase, W.W. Thyroid carcinoma in childhood. A report of 275 cases. Surg Gyn and Obstet 101:217-224 (August 1955).

4. Uhlmann, E.M. Cancer of the thyroid and irradiation. JAMA 161:504-507 (1956).

5. Saenger, E.L., Silverman, F.N., Sterling T., and Turner, M.E. Neoplasia following therapeutic irradiation for benign conditions in childhood. Radiology 74:889-904 (1960).

6. A Review of the Use of Ionizing Radiation in the Treatment of Benign Diseases. Committee Report. National Academy of Sciences. National Research Council. (September 1977).

7. Favus, M.J., Schneider, A.B., Stachura, M.E., Arnold, J.E., Ryo, U.Y., Pinsky, S.M., Colman, M., Arnold, M.J., and Frohman, L.A. Thyroid malignancy occurring as a late consequence of head and neck irradiation: Evaluation of 1056 patients. NEJM 294:1019-1025 (1976).

8. Morbidity from Cancer in the United States, Edited by H.F. Dorn and S.J. Cutler, DHEW Publication No. 590. Public Health Monograph No. 56, Washington, D.C., U.S. Government Printing Office (1958).

9. Third National Cancer Survey: Incidence Data. Prepared by Biometry Branch, Division of Cancer Cause and Prevention, National Cancer Institute. Edited by S.J. Cutler and J.L. Young. DHEW Publication No. (NIA) 75-787. NCI Monograph No. 41 (March 1975).

10. Devasa, S.S. and Silverman, D.T. Cancer Incidence and Mortality Trends in the United States 1935-1974. (In preparation.)

11. Simpson, C.L., Hempelmann, L.H., and Fuller, L.M. Neoplasia in children treated with x-rays in infancy for thymic enlargement. Radiology 64:845-849 (June 1955).

12. Pifer, J.W., Toyooka, E.T., Murray, R.W., Ames, W.R., and Hempelmann, L.H. Neoplasms in children treated with x-rays for thymic enlargement. I. Neoplasms and mortality. JNCI 31:1333-1356 (1963).

13. Toyooka, E.T., Pifer, J.W., Crump, S.L., Dutton, A.M., and Hempelmann, L.H. Neoplasms in children treated with x-rays for thymic enlargement. II. Tumor incidence as a function of radiation factors. JNCI 31:1357-1377 (1963).

14. Toyooka, E.T., Pifer, J.W., and Hempelmann, L.H. Neoplasms in children treated with x-rays for thymic enlargement. III. Clinical description of cases. JNCI 31:1379-1405 (1963).

15. Hempelmann, L.H., Pifer, J.W., Burke, G.J., Terry, R., and Ames, W.R. Neoplasms in persons treated with x-rays in infancy for thymic enlargement. A report of the third follow-up survey. JNCI 38:317 (1967).

16. Hempelmann, L.H., Ha.., W.J., Phillips, M., Cooper, R.A., and Ames, W.R. Neoplasms in persons treates with x-rays in infancy; Fourth survey in 20 years. JNCI 55:519-530 (1975).

17. Hollingsworth, D.R., Hamilton, H.B., Tamagaki, H., et al. Thyroid disease. A study in Hiroshima, Japan. Medicine 42:47-71 (1963).

18. Parker, L.N., Belsky, J.L., Yamamoto, T., Kawamoto, S., and Keehn, R.J. Thyroid carcinoma after exposure to atomic radiation. A continuing survey of a fixed population, Hiroshima and Nagasaki, 1958-1971. Ann Int Med 80:600-604 (1974).

19. Conard, R.A., Rall, J.E., and Sutow, W.W. Thyroid nodules as a late sequela of radioactive fallout in a Marshall Island population exposed in 1954. NEJM 274:1394-1399 (1966).

20. Conard, R.A. Summary of Thyroid Findings in Marshallese 22 years after exposure to radioactive fallout. Part of Conference on Radiation-Associated Thyroid Carcinoma, September 30-October 1, 1976. Edited by L.J. DeGroot, pp. 241-257. Published by Grune and Stratton, New York (August 1977).

21. Albert, R.E. and Omran, A.R. Follow-up study of patients treated by x-ray epilation for tinea capitis: I. Population characteristics, post-treatment illness, and mortality experience. Arch Environ Health 17:899-918 (1968).

22. Albert, R.E., Omran, A.R., Braner, E.W., et al. Follow-up study of patients treated by x-ray epilation for tinea capitis. II. Results of clinical and laboratory examinations. Arch Environ Health 17:919-934 (1968).

23. Shore, R.E. and Albert, R.E. Follow-up study of patients treated by x-ray epilation for tinea capitis. Resurvey of post-treatment illness and mortality experience. Arch Environ Health 31:17-24 (1976).

24. Modan, B., Mart, H., Baidatz, D., Steinitz, R., and Levin, S.G. Radiation-induced head and neck tumours. The Lancet, pp. 277-279 (February 23, 1974).

25. Dobyns, B.M. Radiation hazard - experience with therapeutic and diagnostic ^{131}I. In: Radiation-Associated Thyroid Carcinoma. Edited by DeGroot, L.J. Grune and Stratton, New York, pp. 459-483 (1977).

26. DeGroot, L.J. and Paloyan, E. Thyroid carcinoma and radiation. A Chicago Endemic. JAMA 225:487-491 (1973).

27. National Cancer Institute. Information for physicians on irradiation-related thyroid cancer. Ca - A Cancer Journal for Clinicians 26:1950-59 (1976).

28. National Cancer Institute. Information for Physicians: Irradiation-Related Thyroid Cancer. DHEW Publication No. (NIH) 77-1120 (1977).

29. Radiation-Associated Thyroid Cancer, Proceedings of a conference held September 29-October 1, 1976, Edited by Dr. Leslie J. DeGroot, et al. Grune and Stratton, New York (1977).

30. Gunby, P. I. Meeting reveals growing caution about "routine" thyroidectomies. II. Thyroid cancer increase linked to x-ray exposure. III. Start of atomic age led to more thyroid cancer. IV. Thyroid cancer struggle proceeds on many fronts. JAMA. Medical News 236 (22):2477-2479 (1976).

ARE STATE AND FEDERAL AGENCIES MEETING TODAY'S CHALLENGES? - PART I

Robert Alvarez
Environmental Policy Center
Washington, D.C.

WHY THE ISSUE IS IMPORTANT

Scientists who study health effects of low-level ionizing radiation only seem to agree on one thing: it does have effects, at any dose. Otherwise, they differ--over whether the effects are important or not, what they are, how often they occur, and so on ad infinitum. Some scientists contend that the present radiation protection regulations are not cautious enough, while others see them as representing an overly conservative view of how to protect public health.

More and more questions have been raised over the validity of the "linear hypothesis" that underlies all current standards, that the health effects of a radiation dose are in proportion to the amount of the dose. Because the great bulk of the evidence on human health effects comes from the Hiroshima and Nagasaki bombings and other high dosage situations, scientists have extrapolated in a straight line (hence, linear hypothesis) from high to low doses. Regulatory agencies base their standards on this hypothesis, and on the idea that there is no threshold of exposure below which no effects occur.

Some scientists believe that recent evidence on the effects of low level radiation invalidates or seriously disputes the linear hypothesis (See, for example, K.Z. Morgan, American Industrial Hygiene Association Journal, August 1975, page 567). The newer experimental results, if charted on the above figures, would be speckled above the line on which they would have been expected to fall. Scientists who develop these data, and others who find them convincing, favor stricter radiation protection standards, along with a reexamination of the National Academy of Sciences' Biological Effects of Ionizing Radiation Report (BEIR Report), which gave an official and respected stamp of approval to the linear hypothesis in 1972. It is now argued that the Academy should consider evidence developed in the last 4 years.

The scientific community disagrees about the validity of the very data the regulators need: how much and what kind of effects will result from a certain radiation dose. If anything, the newest data indicates the need for more cautious radiation protection standards. The question is how the human health data will be developed to form the basis for regulations, so they will not be based on hypotheses derived from information on high doses and animal studies.

It would be unethical for scientists to expose a control group of thousands of people to various low doses of radiation and then observe them and their offspring closely. Even if it could be done, there would still be legions of problems like:

1. The difficulty of assessing radiation dose, which varies with the age and general health of the person exposed, the organ involved, metabolic and repair mechanisms, and dozens--perhaps hundreds--of other factors. Dose cannot be measured directly, but rather must be calculated using models employing great numbers of variables; needless to say, there is much dispute about which considerations should be included and in what way.

2. The impossibility, at the present state of knowledge, of distinguishing between radiation's and other factors' effects, except statistically. With hundreds of thousands of toxic substances in the modern American environment, a cancer or other somatic effect can only be linked to its possible sources by looking for correspondences between an unusual level of an environmental factor and an unusual level of a certain health condition.

3. The subtlety of some observed effects, such as a less effective immune system in children whose mothers had x rays during pregnancy. These symptoms may well be attributed to other factors or escape notice altogether.

The above problems alone would make the regulators' task of setting radiation protection standards extremely difficult and complex. But, in addition, health effects of radiation may take years or even generations to develop. Even if a controlled study were begun immediately, it would take several decades before anything approaching full information on doses and effects would be available.

Such a study will never, and should never, be conducted deliberately--but evidence must somehow be collected if standards are to be based on scientific facts instead of extrapolation and hypothesis. The spread of nuclear power makes sound standards all the more important, since more and more people may be affected by radiation exposure. While the controlled study is out of the question because it would be considered unethical, in effect the experiment is being conducted now in a very unsystematic way. People, particularly workers, are exposed to increasing radiation doses from a widening array of sources, including widespread fallout. If scientists are right in assuming some effects at any dosage, then many people must be subject to them. Possible effects of radiation--including cancer and subtle changes in vulnerability to other diseases--are not being detected as such because they cannot be distinguished from effects of other environmental agents. Even if they could be, the information would be incomplete because some effects will not even appear for years or decades.

Since people are being exposed to low-level radiation and are experiencing some effects, even if they are not aware of them, this experiment should be documented, and the results should be used to set radiation protection standards. Two kinds of data need to be collected: (1) whatever can be used to calculate the dose a certain population receives, which means monitoring radiation in food, air, water, workplace environments and others; and (2) public health data which accounts during several generations not only for a wide range of illnesses, but also for other factors such as lifespan and fertility.

Radiation dose/effect relationships will only become clearer by comparing rates of certain types of cancer and other possible effects to the doses calculated from monitoring information. The same effects may have many different sources, and only statistical evidence can narrow down which may be caused by radiation. For example, a high rate of a certain birth defects may appear in a location where people also get an above average radiation dose. Researchers would then have a clue to look for that correspondence elsewhere, and might find that there is in fact a causal relationship.

If the effects of low-level radiation prove insignificant after monitoring and public health studies are done, the public will be assured that it is not being exposed to a hazard. If the results lean in the other direction, protective standards must be strengthened, and major energy and public health issues will require reexamination. These stakes are too high to permit ignoring data which is waiting to be gathered.

SCOPE AND BACKGROUND OF THIS STUDY

The necessary beginning of an investigation of the health effects of low level radiation is to decide whether enough monitoring and health research is already being done. The present study is a part of the legal, budgetary and Federal and State program information which needs to be collected before such an assessment can begin. It is limited, by practical rather than substantive considerations, to include only routine monitoring in and near nuclear power reactors during FY 1974-1976 by the Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC), the Energy Research and Development Administration (ERDA), and the old Atomic Energy Commission (AEC). Certain rather specialized forms of monitoring were excluded, such as of packages containing radioactive materials. This study emphasizes; (a) how jurisdiction over monitoring is divided between Federal and State agencies, and among the Federal agencies involved; (b) current and important pending Federal regulations which require monitoring and keeping the resulting records; (c) what the Federal agencies have done and how their budgets have fluctuated over the study period; and (d) a few State programs and their suggestions for change in their own and Federal policies.

The three kinds of monitoring covered by this study are environmental, occupational, and effluent, and each has its own immediate purposes and problems. Ultimately, the goal of all three is to calculate, as accurately as possible, radiation doses to humans. Occupational monitoring determines whether or not a worker is getting a higher dose than regulations allow. Since different kinds of radiation travel at different speeds and have different effects on various parts of the body, a unit of measurement for dose, the rem, has been devised to even out exposure from these various sources. Standards for how many rems a worker may receive are expressed in terms of time; i.e., 5 rems per year. Measurement problems abound: For example, a worker wearing a film badge on the chest may be exposed to slow moving beta radiation on the back which never registers on the badge.

Effluent monitoring measures the amount of overall radiation and of specific radionuclides in the water and air leaving the reactor, providing the basis for calculating dose to the general public. Models are established for the "critical pathways" by which humans receive doses from air and water. Among the problems involved is assessing the way effluents will travel, which is extremely difficult for both gasses and liquids; for example, if a chance wind carries gaseous effluents to a population center instead of blowing them away as usual, obviously the dose there will be affected.

Environmental monitoring includes samples of milk, soil and foods as well as ambient air and water. By the time a problem of high levels appears in environmental monitoring, humans have already been exposed and the time for preventive action is past. The main purpose of such monitoring are (1) to confirm or challenge the results of dose calculations based on effluent measurements and (2) to observe the long-term buildup of radionuclides in the environment. The major difficulty in performing environmental monitoring is that levels are usually such that present instruments can barely detect them, if at all.

Although monitoring is essential to meaningful protection standards, it is by no means the answer to all the regulatory questions and problems. As discussed above, there are many scientific and technological uncertainties yet to be overcome. Even given the best information current instruments can offer, there is a great deal of room for dispute over what that data means in terms of the dose humans are subject to--not to mention what the dose may do to them or succeeding generations.

Beyond those scientific controversies, many different policy concepts can be used for setting radiation protection standards, such as:

1. Limiting the "environmental dose commitment," an idea developed by EPA, which is the "total projected radiation dose to populations committed by the irreversible release of long lived radionuclides in the environment." (Environmental Radiation Dose Commitment. EPA, 1974, p. xii.)

2. Limiting the dose to the most exposed individual, which would almost invariably be a worker in a nuclear facility.

3. Limiting the dose to an individual at the boundary line of a nuclear facility site.

It should be noted that, while humans are thought to be the animals most sensitive to radiation, any change in that assumption could necessitate standards for other species as well.

Whatever the variety of views on these policy concepts, a major consideration in any future standard setting will be the civil liberties implications of scientific findings on how various populations are affected by radiation. Some questions have already been raised in the case of whether or not stricter standards for radiation protection should be set for pregnant women than for other workers. Is it an invasion of privacy for the employer to investigate an employee's fertility or pregnancy status? Can a woman consent in advance to exposure that may be hazardous should she become pregnant? If a woman, not knowing she is pregnant, is exposed and elects an abortion, should the employer be compelled to pay for it? The questions can go on almost forever; discrimination is bound to emerge as a possibility in radiation protection regulations, since age and fertility are already known to be important variables in determining the effects of a given dose.

Obviously, the whole cluster of issues around low-level radiation is in controversy--from the most basic scientific facts about how a certain dose will affect a particular human organ to complex policy questions involving equity and sex discrimination and how strictly standards should be set. Although this study only provides data about one narrow aspect of present policies, we hope it will lead to a complete project to gather information on monitoring in all situations, and on public health data to match with the monitoring results.

RESPONSIBILITY FOR MONITORING

Division between Federal and State Governments

States do environmental and effluent monitoring related to nuclear power plants for their own information and under contract for the Federal Government's enforcement purposes; however, they have been barred from setting State standards requiring monitoring of nuclear facilities that are stricter than Federal ones. The Atomic Energy Act says that the Commission will not encroach on any Federal, State, or local agency's authority over the power produced by nuclear facilities; at the same time, "this section shall not be deemed to confer upon any Federal, State, or local agency any authority to regulate, control or restrict any activities of the Commission" (42 USC 2018).

In 1971, the U.S. Court of Appeals ruled that the AEC's authority to regulate radioactive releases was "exclusive so as to preclude State action." (Northern States Power Company, Appellee, v. State of Minnesota, the Minnesota Pollution Control Agency et al., Appellants. 447 F2d 1143. No. 71-1093, U.S. Court of Appeals, 8th Circuit, 9/7/71.) The point was raised because a utility, when it asked the State of Minnesota for a discharge permit for its nuclear power plant, was presented with a batch of State effluent and monitoring regulations far stiffer then the AEC's. Eighteen other States joined Minnesota in defending their rights to set such standards. The court majority, which ruled for the utility, reasoned that the doctrine of preemption excluded State action; the dissent held that the lack of a preemption clause in the Atomic Energy Act was a deliberate omission, especially since all non-radioactive forms of pollution from nuclear power plants are subject to State regulations. The Supreme Court upheld the majority decision in an order (405 US 1035).

Legislation that would allow the States to set their own standards has been proposed on and off since 1969, but has never been enacted. For example, after the Joint Committee on Atomic Energy failed to deal with such proposals for 4 years, House members took the issue to the floor directly on June 25, 1973. Advocates of nuclear power pointed to problems of non-uniform regulation, contending that a few retrogressive States could slow the energy supply for the whole country. In any event, they argued, the AEC had already set the standards "as low as practicable," and who could get any lower than that? Proponents of the legislation, on the other hand, rested their case on the right and responsibility of States to protect the health and safety of their citizens. They contended that States would not be overzealous on standards because they would then deny themselves revenues and other benefits of having power plants; moreover, technology then allowed for substantially lower emissions than the AEC suggested in its specific numerical guidelines, and States should have a chance to require that the best available technology be used. The measure failed by 266-136.

Until such legislation passes, or the Supreme Court reverses itself, it seems that the most active role States can look toward is more participation in monitoring and other Federal programs.

Division among Federal Agencies

Division of responsibility for monitoring low-level radiation in and near nuclear power plants has been controversial and confusing since the creation of the Environmental Protection Agency in 1970, and has only become more so since the dismemberment of the Atomic Energy Commission in 1975.

When EPA was founded under Reorganization Plan 3 of 1970, it was given the responsibility of:

1. The Federal Radiation Council, whose job was "to advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance to Federal agencies in the formulation of radiation standards..." (73 Stat 690.)

2. The Bureau of Radiological Health in the Food and Drug Administration, except "insofar as the functions...pertain to (A) regulation of radiation from consumer products, including electronic product radiation, (B) radiation as used in the healing arts, (C) occupational exposures to radiation, and (D) research, technical assistance, and training related to clauses (A), (B), and (C)." (Reorganization Plan 2 or 1970, Section 2.)

3. The AEC's Division of Radiation Protection Standards, "to the extent that such functions of the Commission consist of establishing generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposure or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." (Ibid.)

Of special interest is the fact that while EPA was given authority for some standard setting, enforcement remained with AEC; thus, any standards EPA promulgated could be effectively gutted if AEC did not enforce them.

The two agencies charted their territories on radioactive water pollution in a Memorandum of Understanding published in the January 29, 1973 FEDERAL REGISTER. EPA agreed to speed up its permit granting and effluent limit-setting process for AEC facilities, with AEC reiterating its willingness to accept EPA decisions under the Federal Water Pollution Control Act. There is also a vague paragraph to the effect that there are many factors to be weighed, other than water quality, in establishing effluent limits and issuing discharge permits--and EPA should remember that those factors are "appropriate for consideration" when AEC facilities are evaluated.

The next formal attempt to delineate EPA and AEC responsibilities was expressed in two memoranda published in fall 1973, with regard to AEC's helping EPA get information necessary for standards setting, EPA accompaniment of AEC personnel on inspections of licensed facilities, and the Agencies' advising each other on matters of mutual concern. Although the two memoranda were executed within 3 months of each other, there are dramatic differences between them. The first (published September 11, 1973), for example, promises that "AEC will take appropriate action to assure that AEC licensed facilities are operated in such a manner that routine radioactive discharges therefrom do not exceed generally applicable environmental standards established by EPA, outside the site boundary, for the protection of the general environment form radioactive material." The second (in the November 29, 1973 FEDERAL REGISTER) merely says that AEC facilities will be "operated under applicable laws so as to comply with such standards." While the earlier memorandum speaks of joint studies, the second only allows EPA to enter plants under very specific conditions, and promises to furnish the Agency with AEC's data on pollution only "to the extent feasible." EPA is specifically excluded from entering plants to establish "operating conditions for AEC facilities in meeting generally applicable environmental standards." Rather, AEC is responsible for all standards setting and monitoring within site boundaries, and for meeting EPA's generally applicable environmental standards at the boundaries.

EPA and AEC publicly came into open conflict in late 1973, when EPA proposed standards for each of three classes of facilities with common emission and control characteristics: fuel supply facilities, light water reactors, and reprocessing plants. AEC disputed EPA's action, contending that the standards did not fall into the category of "generally applicable environmental standards" permitted in the Reorganization Plan. Despite numerous attempts, the agencies were unable to come to any agreement, and referred the issue to then-President Nixon.

On December 7, 1973, the Director of the Office of Management and Budget made it perfectly clear "on behalf of the President" the EPA had overstepped: "EPA has construed too broadly its responsibilities." AEC was directed to proceed with issuing standards for the uranium fuel cycle components, while EPA was told to abandon its proposals and focus instead on "setting standards for the total amount of radiation in the general environment from all facilities combined in the uranium fuel cycle, i.e., an ambient standard which would have to reflect AEC's findings as to the practicability of emissions controls."

The New York Times reported on December 12 that a "reversal of policy" had been ordered by the President, and editorialized on December 18:

> "The pressures brought about by the energy shortages to undercut the antipollution victories of the past few years are reflected anew in the Administration's decision to transfer authority for policing radiation levels of nuclear power plants from the EPA to the AEC....When the EPA had the task of setting radiation standards, the country at least had the benefit of relatively independent scrutiny and judgment. The AEC by contrast is both a regulatory agency for civilian nuclear power plants and the government's chief promoter of their development. A conflict of interest is inherent in these two functions..."

Congressional reaction to the OMB directive was immediate if not widespread. Rep. John Seiberling (D-Ohio) stated on December 18, 1973 his intent to offer an amendment to the Energy Reorganization Act which would restore to EPA the authority taken away by the memorandum. Seiberling's proposal failed, as have subsequent attempts.

The Energy Reorganization Act of 1974 made the jurisdictional situation even more complex by dividing up the AEC. The main idea behind the reorganization was to separate regulatory (now NRC) from promotional (now ERDA) divisions, which many felt were inappropriately combined in AEC. The Nuclear Regulatory Commission (NRC) took over the "licensing and regulated regulatory functions" (P.L. 93-438, 201(b)2(f)), and got jurisdiction over some facilities of the promotional arm(specifically, over ERDA's demonstration reactors which were not already built, when operated as part of generation facilities and a few other types of plants).

As matters stand, ERDA and NRC are each generally responsible for standards setting and for checking up on their contractors' and licensees' monitoring programs within site boundaries (sometimes using a State under contract). In addition to being required to comply with standards applying to all plants, each plant has its own specifications to meet. Outside the site, NRC and ERDA cooperate with other Federal and State agencies, including EPA, to monitor compliance with EPA's general standards for the general environment. The failure of a recent court attempt to assert EPA's right to control specific radioactive discharges from any source, including NRC or ERDA facilities, implies that jurisdictional changes will be made only through legislative action, if at all. (Russell Train et al. v. Colorado Public Interest Group. 96 S.Ct. 1938 (1976), #74-1270.)

CURRENT FEDERAL REGULATIONS

Environmental Protection Agency

Occupational Monitoring

About 2 years ago, EPA decided to review and update currently applicable Federal guidelines on occupational exposure to radiation, which were set by the Federal Radiation Council in 1960. An Interagency Committee was formed, staffed by one professional at EPA. As of this writing, it had not yet publicly issued any proposed revisions. A working paper was under review by the various agencies involved, and it was hoped that something might be published in the FEDERAL REGISTER in mid-1977.

Effluent and Environmental Monitoring

Areas outside the boundaries of nuclear power plant sites are subject to EPA's generally applicable standards for air and water pollution (40 CFR Part 61 Subpart C, and 40 CFR 125).

As discussed in the section above on division of Federal responsibilities, EPA's attempts to set standards for components of the nuclear fuel cycle were thwarted by the Office of Management and Budget in December 1973. However, proposed standards applying to the entire fuel cycle were published on May 29, 1975 (40 FR 23420), and EPA held hearings on them in early 1976. The standards would:

1. Limit the annual dose equivalent to the whole body (to 25 millirems), to the thyroid (to 75 millirems), and to any other organ (to 25 millirems). This would have the effect of limiting population and individual exposures beyond plant site boundaries, specifically those resulting from short-lived fission produced and naturally occurring materials, and from transportation of any radioactive material.

2. Limit the quantities of krypton-85 (to 50,000 curies), iodine-129 (to 5 millicuries), and certain long-lived transuranic radionuclides released per gigawatt year of power produced by the entire fuel cycle. The principle is to restrict human exposure--particularly to large population groups over long periods of time--and accumulation of environmental burdens. EPA estimates that its proposed standards would significantly reduce the number of potential health effects of the nuclear fuel cycle; through the year 2000, for example, it is estimated that effects of controllable long-lived radioactive materials would be cut from 1040 to 20. (See the Draft Environmental Statement on Environmental Radiation Protection Regulations for Normal Operations of the Activities in the Uranium Fuel Cycle, EPA, 1975, page 82.)

Like previous standards, the current proposals are based on the nonthreshold linear hypothesis, that effects are in proportion to dose, and every dose has an effect. However, they are an important departure, in that previous standards have been directed almost solely at the dose to individuals. In its advance notice of proposed rulemaking in the May 10, 1974 FEDERAL REGISTER (39 FR 16906), EPA explained why current regulations are inadequate in its view: they do not "require sufficiently explicit consideration of total population dose," and they do not deal adequately with long-term impacts of the release of long-lived radionuclides. EPA also noted that AEC (which had not yet been split) would be responsible for implementing any EPA proposals by its policies in issuing and enforcing licenses for nuclear reactors, including technical specifications for effluent points and other design criteria.

When the proposed rules were published on May 29, 1975, EPA promised to review, and, if necessary, update them every 5 years--an approach that could answer allegations that standards are quickly outmoded and have not been reviewed in light of, much less changed in response to, new scientific evidence as it was developed. A detailed explanation of the rationale for the EPA standards was provided, including the basic cost benefit approach: "the standards generally represent the lowest radiation levels at which the Agency has determined that the costs of control are justified by the reduction in health risk" (40 FR 23421).

Although some of the standards admittedly rely on technologies that have not yet achieved routine use, they also provide for temporary increases above the regular limits "when the public interest is served, such as to maintain a dependable source of continuous power or during a power crisis" (40 FR 23423).

As of fall 1976--almost 3 years after the Office of Management and Budget Memorandum--EPA had not promulgated any of the proposed regualtions discussed above, which would provide environmental radiation protection for nuclear power operations.

ERDA and NRC

ERDA and NRC will be discussed together to show the differences between the two Agencies' regulations and policies. Much of the material is derived from the NRC Regulatory Guides and the ERDA Manual, which are explanatory documents intended for use by licensees and contractors. Rather than providing an all-inclusive analysis, the comparison is designed to highlight some of the important differences between the Agencies.

Occupational Monitoring

1. General philosophy

The general philosophy underlying NRC's occupational standards is that exposure should be kept "as low as is reasonably achievable," with the sum of doses to all individuals being taken into account as well as the dose to each person. (For example, it might be possible for a job to be done by two people, each exposed to 3 rems, instead of having one person exposed to 4 rems. Using two people is not necessarily preferable simply because it minimizes each individual's exposure.) To clarify how the "reasonably achievable" standard could be met, Regulatory Guide 8.8 gives suggestions about facility and equipment design, plans and procedures.

Most important, "a specific individual (i.e., the Radiation Protection Manager) should be given explicit responsibility and authority for ensuring that exposures are as low as is reasonably achievable." That person must be "an experienced professional in applied radiation protection at nuclear facilities dealing with radiation protection problems and problems similar to those at nuclear power stations."

The ERDA Manual does not require a special person, but rather that "operations supervision should have a good understanding of the radiological characteristics and potential safety problem areas associated with their program..." (0524 Part V). The Manual Chapter on "Standards for Radiation Protection (0524) and its appendix are limited in scope; they "apply to routine operations. They do not apply to certain specific activities such as those essential to the national security..." Rather than NRC's "as low as is reasonably achievable" approach, the objective of ERDA regulation is to "assure that radiation exposure to individuals and population groups is limited to the lowest levels technically and economically practicable." The "Guidance on maintaining exposures to as low as practicable" (Part V of 0524) includes discussion of facility design, operating equipment, and monitoring equipment.

2. Standards in the workplace

The agencies' standards in restricted or controlled workplace areas compare as follows:

ERDA	Rem per Year	Rem per Cal. Quarter	Rem per Cal. Quarter	NRC
Whole body, head and gonads, lens of eye, red bone marrow, active blood forming organs	5	3	1 1/4	Whole body, head and trunk, active blood forming organs; lens of the eye; or gonads
Unlimited areas of skin (Except hands and forearms), other organs, tissues, and organ systems (except bone)	15	5	7 1/2	Skin of whole body

ERDA	Rem per Year	Rem per Cal. Quarter	Rem per Cal. Quarter	NRC
Bone	30	10		
Forearms	30	10	18 3/4	Hands and forearms; feet and ankles
Hands and feet	75	25		

(The ERDA information comes from 0524, Part I, A, 1; NRC is from 10 CFR 20.101(a).) Both Agencies permit licensees and contractors to allow a higher whole-body dose than is set above, provided that the average dose per year since age 18 does not exceed 5 rems per year. ERDA, however, requires the express permission of its Division of Operational Safety's Director. NRC allows the licensee to use the exemption without special permission as long as the whole body dose does not exceed 3 rems per calendar quarter and certain records are kept.

As far as monitoring to enforce the standards is concerned, under NRC's regulations, "each individual who enters a restricted area under such circumstances that he receives or is likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable value specified" must be monitored. ERDA casts a wider net, requiring monitoring "where the potential exists for the individual to receive a dose or dose commitment in excess of 10 percent of the quarterly standards."

3. Reporting requirements

Both agencies require that licensees or contractors file, by March 31 of each year, a report on the previous year showing how many people were monitored and how many fell into each of 12 exposure ranges. ERDA also requires a "summary of exposures resulting in the internal body depositions of radioactive material for calendar year x."

When employees exposed to radiation change jobs, both agencies require that they be informed of the extent to which they have been exposed. However, the time limits on informing them are different: NRC requires that it be done within 90 days of termination or 30 days after determining the dose, whichever is earlier. ERDA, on the other hand, allows 30 days after termination or 30 days after determination, whichever is later.

Special regulations cover reporting of overexposures and other nonroutine incidents.

Environmental and Effluent Monitoring

1. General Philosophy

NRC changed its basic criterion for effluents from nuclear facilities as of January 19, 1975 as follows:

> Old definition: "as low as is practicably achievable taking into account the state of technology, and the economics of improvments in relation to the benefits to the public health and safety and in relation to the utilization of atomic energy in the public interest." (10 CFR 20.1, prior to 1/19/75.)
>
> New definition: "as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest." (New language is underlined. 10 CFR 20.1, after 1/19/76. Published in 40 CFR 58847 on December 19, 1975.)

In explaining the change (40 FR 33029, August 6, 1975), NRC said it merely followed the precedent of the International Commission on Radiation Protection, which had just issued a publication taking social and economic considerations into account, and making what they considered a semantic change from "practicably" to "reasonably" achievable. The Commission referred to the first phase as "the older, less precise terrminology."

The ERDA Manual still uses the "as low as practicable" standard in Chapter 0524, explained as "the lowest levels technically and economically practicable" (Section 012). The objectives of the monitoring program are to determine compliance with ERDA and other Federal standards, and "the adequacy and effectiveness of effluent treatment and control, environmental protection, and efforts to achieve levels of radioactivity which are as low as practical (sic)" (0513-01).

2. Effluent standards

Both ERDA and NRC confine the annual dose equivalent for a non-employee to 0.5 rem to the whole body, at maximum probable exposure points. Exceptions are permitted, although under different circumstances. NRC will approve limits above the ones set if the applicants demonstrate that they have made "a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and that it is not likely that the radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits..." The ERDA Manual states instead that "there may be situations where it is not feasible or desirable to evaluate the exposure of individuals and samples of exposed populations to effluents to assure compliance..."; then, the contractor may use the as low as practicable standard at the point where effluents pass beyond the boundary.

Because the original siting and design of a plant will largely determine the potency of radioactive effluents after it is built, ERDA and NRC have criteria to judge in advance whether possible hazards from effluents will be minimized. NRC's regulations include a Section (10 CFR 50.34a) specifically on "Design Objectives for Equipment" to control releases of radioactive material in effluents. For ERDA contractors, the old AEC Manual Appendix 6301, "General Design Criteria," is used, with chapters on air and water pollution control facilities.

The technical specifications on just how much radioactivity may be released from a plant are part of the original plans, but both agencies have additional broad ground rules. NRC requires that a proposed environmental surveillance program be included in the license application, along with a reporting schedule. Although ERDA provides guidance on monitoring locations and the type and frequency of sampling, methods of sample collection and analysis are deliberately left out since "they do not lend themselves to development of broad guidance but must be tailored to the monitoring requirements in each specific situation."

In 1975, the U.S. Court of Appeals held that the AEC could not determine "that any particular positive level of emissions satisfied its requirements in all cases" under the as low as practicable standard (York Committee for a Safe Environment et al.v. U.S. AEC and U.S., Philadelphia Electric Company, Intervenor. 527 F2d 812). Hence, the Agencies' suggestions about what numerical concentrations are appropriate are not standards that must be met, but merely guides. ERDA's Annex A to 0524, "Concentrations in air and water above natural background," gives figures for all elements in air and water, in controlled and uncontrolled areas; the comparable NRC document is Appendix I to 10 CFR 20, "Numerical guides for design objectives and limiting conditions for operation to meet the criterion as low as is reasonably achievable..." In addition, there is guidance on dose calculation, the dispersion of effluents, and other technical issues.

3. Environmental standards

According to ERDA, its purposes for environmental monitoring are to determine "whether containment and control of site operations are functioning as planned, (2) whether and to what extent environmental levels of radioactivity released from AEC sites comply with applicable standards, and (3) the overall impact of operations on the environment." Another common purpose is to check out whether the models used to calculate the dose to humans are working. The amount of environmental monitoring to be done around ERDA plants is to be determined by the field offices and the contractor, "based on hazard potential, quantities and concentrations of materials released, specific local public interest or concern, and extent and type of utilization of affected offsite air, land and water."

NRC's Regulatory Guide 4.1, "Programs for monitoring radioactivity in the environs of nuclear power plants," discusses the basis for licensee's programs. The indicator medium concept is used, meaning that the licensee should monitor organisms and media that are sensitive and reliable measurement devices for how much is cycling through a particular pathway from the power plant to humans. In addition, if they are not already included, "the program should cover elements of the ecosystem for which a causal relationship between plant operation and adverse change is established or strongly suspected." Programs should consider the possibility of buildup of long-lived radionuclides in the environment, and potential radiation exposure to plants and animals. Correlations should be established between levels of radiation measured in the environment and radioactive releases from plant operation so effluent monitoring results can be confirmed by environmental data. A series of guides titled "Measurement of radionuclides in the environment" has been issued for a number of individual substances, including discussion of the regulatory position and techniques for collection, extraction and measurement.

4. Reports of effluent and environmental monitoring results

Annual environmental monitoring reports are required by both NRC and ERDA, although ERDA's Manual includes a more extensive description of what is required than the NRC Guides. The ERDA Report is "to interpret and summarize the levels of radioactivity...in the environs of AEC sites resulting from site operations in relation to applicable standards and relevant parameters, such as background and natural radioactivity." Specifically, the Report should include an assessment of the radiation exposure of the public which "could have resulted" from operations during the year, and it should provide realistic estimates of fence post dose, dose in individuals and groups where the highest dose rates occur, and the whole body dose 80 kilometers away.

The comparable report to NRC "shall include summaries, interpretations, and statistical evaluation of the results of the radiological environmental surveillance activities for the report period, including...an assessment of the observed impacts of the plant operation on the environment," and tabulate and summarize the results of samples.

Reports of effluent releases are handled differently: NRC facilities must report semiannually on the quantities of all effluent releases, meterological conditions when gases escape, and calculated offsite dose to humans. ERDA requires instead an annual report, "Radioactive effluent/onsite discharge data," including detailed information on specific nuclides, their concentrations, maps showing monitoring sites, and "pertinent descriptive and interpretative information which are not adequately described on the forms."

FEDERAL PROGRAMS

EPA

Over the last 3 years, the goals and activities of EPA's monitoring program have narrowed and diminished. In general, monitoring is more source oriented, especially to nuclear facilities, than ever before. EPA's major concern is to determine levels of radiation from specific sources, identify the critical pathways, and then assess the impact on the environment--rather than the general baseline studies emphasized in FY 1974 and earlier. There is more concern now for an integrated approach, considering the population dose from all sources, both ionizing and nonionizing, background and generated. At the same time, many activities have been dropped from EPA's justification of its request to Congress:

* a mill tailings program, to measure levels of radiation in areas where mill tailings were used in construction, and to take remedial action;

* Radiation Data and Reports, a monthly publication giving the results of monitoring nationwide along with articles by State and Federal officials (now an annual report);

* assessment of environmental radiation following accidental releases of radioactivity from nuclear facilities.

The 1976 plan ended up being limited to collecting and analyzing data on radioactivity in air, water, and milk; establishing an actinide soil monitoring program; and completing dose summaries from all sources and comparing them with standards. This is modest indeed compared to the six 1974 objectives, which included evaluating the environmental effects of nuclear power plant operation on people and continuing quality assurance efforts. Another important cut was in State programs, which were not included at all in the 1975 general description of activities; although helping States to develop an emergency response plan for radioactive incidents was listed in the 1974 goals, it was not among the 1975 accomplishments.

There were no real increases in EPA's Radiation Abatement and Control: Monitoring budget--just enough to cover a Government-wide pay raise--in FY 1974 and 1975, and there was a substantial cut in FY 1976 as a result of eliminating Radiation Data and Reports. It should be noted that the comparative numbers below are in real, not constant dollars:

FY 1973:	$1,579,600
FY 1974:	$1,549,300
FY 1975:	$1,558,500
FY 1976:	$1,407,800

In FY 1974, EPA published "Environmental Radiation Dose Commitment: An Application to the Nuclear Power Industry," which outlines numerical values of key parameters for specific radionuclides as well as discussing the background of the new concept. The two customary ways of looking at the impact of radioactive effluents are in terms of maximum dose to individuals, and summing individual doses, rather than including, as the environmental dose commitment does, the additional impact in subsequent years due to buildup and persistence of some radionuclides.

Another major publication was the multi-volume "Environmental Analysis of the Uranium Fuel Cycle," completed in 1974. Each element of the fuel cycle was examined, including nuclear reactors (that volume was published in November 1973), and formed the basis for later regulation proposals. Discussion of EPA's relationship to the nuclear industry was toned down a good deal from the previous year: rather than speaking of determining compliance with EPA regulations, the FY 1974 justification concentrates on mathematical calculation of current levels of exposures from operations in the fuel cycle.

In collaboration with AEC, EPA conducted field studies at several nuclear facilities, (1) to develop measurement techniques for effluents, (2) to validate its models of how doses are calculated from effluent and environmental data, (3) to characterize effluents by element, (4) to determine the extent to which current technology can meet standards, and (5) to study waste disposal.

The core of the program, in FY 1974 and subsequent years, is the Environmental Radiation Ambient Monitoring System (ERAMS). Formed in July 1973 from a number of smaller, fallout-oriented networks, the System was trimmed to focus almost exclusively on areas around nuclear facilities. State and local governments collect samples for ERAMS and send them to EPA for analysis. Monitoring results were published monthly until December 1974, when an annual report policy was instituted. Because ERAMS is nationwide and has been used regularly in various forms for some years, the data compiled is useful for checking against the nuclear industry's monitoring results.

The ERAMS program continued in FY 1975, along with field studies at nuclear facilities to improve information on radionuclide levels associated with specific kinds of sources. A dose assessment plan was developed, using a Comprehensive Dose Computational System to estimate projected risks from all sources. A complementary program to devise exposure pathway models continued.

EPA staff began examining occupational exposure to radiation following formation of an Interagency Committee on that subject. Among the major issues defined were:

-- how the radiation protection guide should be calculated, using the comparative risk rather than cost benefit approach;

-- misuse of the accumulated exposure rule of 5 rems, when employers would hire a worker for a very short time, expose him or her to 5 rems and dismiss the worker;

-- determining the meaning of "as low as is reasonable achievable" in the occupational context; and

-- formulating regulations which would allow exceeding the standard under some circumstances.

Another major new development in FY 1975 was publication of the "Draft Environmental Statement: Environmental Radiation Protection Requirements for Normal Operations of Activities in the Uranium Fuel Cycle." The Statement includes discussion of the rationale for the standards, technical considerations, and the anticipated impact.

FY 1976, along with a hefty budget cut, brought reduced programs. EPA Assistant Administrator for Air and Waste Management, Roger Strelow, testified that "We have a new and growing monitoring program, which we refer to as the dose commitment, dealing with overall dose commitment to the population from all radiation sources, including natural sources, background sources, and everything else. This effort is moving forward aggressively and is not in any way impaired by these cuts. The type of cuts we are talking about, again, are on the fringes of this type of activity. There simply is a lot of monitoring work that was inherited from the various component agencies, and faced with budget stringencies, we have tried to pare around the edges" (DHUD Appropriations, FY 1976, Senate Appropriations Subcommittee, page 1093).

Despite Strelow's optimism, the 1976 plan presented in the justification to Congress was pared down greatly from previous years to the objectives mentioned above (collecting and analyzing air, water, and milk data; establishing actinide soil monitoring; completing dose summaries and comparing them to standards). However, in the course of the year, important publications were completed in three areas:

EPA/ORP Program Statement, published in May 1976. This document clearly delineates the background of the radiation problem, including health effects, and defines the specific goals and objectives of the program, explaining the position EPA takes on a number of controversial scientific issues.

Environmental Radiation Protection for Nuclear Power Operations: Supplementary Information, published January 5, 1976. In addition to a full discussion of the dose-effect assumptions used as the basis of the proposals, a number of technical issues are addressed, such as control of krypton and iodine discharges from nuclear fuel reprocessing facilities. The most interesting section for a lay person is the first one, on implementation and verification of compliance with the proposals.

Radiological Quality of the Environment, published May 1976. Perhaps the most ambitious of the three publications, this was the first attempt to draw the whole picture of how much radiation Americans are exposed to, and to measure that data against protection standards. Each element of the uranium fuel cycle is covered, as well as fallout, medical radiation, consumer products and more.

All in all, as noted in the first part of this section, the EPA radiation monitoring program has been curtailed over the last several years, with less money available to achieve its ever narrower goals. The information program to distribute monitoring data monthly has been cut back to allow only for annual reports--which, aside from not being timely, do not include articles. These changes are especially unfortunate because, as noted in the ORP Program Statement (page 37): "The ERAMS and the special (field) studies conducted at operating nuclear facilities are the only independent assessment of environmental radiation and population exposure carried out as a continuing activity outside of the energy production industry."

FEDERAL PROGRAMS

AEC/NRC

As depicted in Congressional hearings for FY 1974-76, the AEC/NRC regulatory function has changed somewhat but not dramatically, with some shifts in personnel and funding as well as changes in administrative arrangements. In the FY 1974 hearings, AEC representatives reported that the Regulatory Division had been reorganized into three broad functional directorates. The Operations Directorate was made responsible for inspections to assess licensee compliance with all kinds of standards, including safety and environmental protection, in all facilities licensed by AEC. The Division cited the need to build an independent regulatory capability as a reason for their increased budget request.

In the next year, the budget was based on the same level of inspectors' time per facility. AEC had wanted to expand its inspection staff, but the Office of Management and Budget cut 11 positions specifically for monitoring of environmental and effluent radiation levels; even the defenders of the Administration budget conceded that it was an adequate, not optimum, plan.

In 1975, the AEC Operations Directorate became the NRC Inspection and Enforcement Office, and during FY 1976 hearings the Office requested 125 new positions, many to be used for checking on nuclear power plants. Because of regulatory experience, which included 861 unusual or abnormal occurrences in one year, NRC decided to broaden and intensify its inspection program. However, it was explicitly stated that "The total system of inspection of nuclear facilities includes both a very heavy investment of manpower by the private sector as well as a more limited investment of manpower by the Federal Government...The Federal Government portion of the inspection program is explicitly designed to provide assurance that the much larger program of the private sector is honestly and effectively carried out" (Public Works, FY 1976, House Appropriations Subcommittee, 4/21/75, page 26). The NRC depicted itself as largely inspecting the industry inspection system, rather than emphasizing direct checking of the results of the system.

The program now leans heavily on contracts with the States to perform confirmatory environmental monitoring around (sometimes in) nuclear power plants. While the terms of individual contracts vary, in general NRC provides financial support for operating expenses and States provide appropritate technical expertise. Fifteen States participate in the cooperative program, covering 35 of the 48 sites nationwide that house operating power reactors. The funding levels have increased to $221,000 in FY 1976 and the transition quarter, from $180,000 in FY 1975 and $141,000 in FY 1974.

Complementing the States' monitoring, NRC itself inspects reactors. These inspections usually involve 2 or 3 days at a reactor site, and result in written notification to the licensee of inspection findings (also available to the public). Operating plants are inspected about once a year. In addition to a plethora of other areas, including staff qualifications and training, equipment installation and testing, NRC looks at effluent/environmental protection--specifically review of licensee management control procedures and practices, development and implementation of monitoring systems, and non-radioactive effluents and releases.

Funding for the entire Inspection and Enforcement Office and its predecessor--both of which contain many important elements other than the issues addressed in this study--has been increased over the last 3 years from $12,433,000 in 1974 to $16,634,000 in 1975, and $21,415,000 in 1976. About 30 NRC person-equivalents were working on reactor effluent and environmental monitoring activities in FY 1976, covering both radiological and non-radiological contamination, an increase over 22 in FY 1975, and 16 in FY 1974. Also, the percentage of overall inspector-years spent on monitoring has increased from 13 percent in 1974 to 20 percent in 1976. Each inspector is performing more inspections per year, about 15 in 1976 versus 12 and 10 previously; 22 percent of their time was spent onsite, a slight increase from FY 1975. It is difficult to evaluate the meaning of these changes in terms of the effectiveness of the programs: for example, more inspections per person may either mean that they are briefer and more superficial--or that they are more efficient and less burdened with paperwork.

A better measure, perhaps, is the number of inspectors per operating reactor. It has fluctuated from 2.44 up to 3.00 and then down to 2.71 in FY 1976, while there has been a slow but steady decrease in the ratio of inspectors to total sites, both operational and preoperational. (Preoperational monitoring and inspection are extremely important, because they make it possible to detect concentrations that exceed normal background once the plant is actually operating.)

Despite these ups and downs and the increasing number of reactors, the frequency of inspections and their results have changed very little over the last 3 years. Plants have been inspected for effluent/environmental protection about equally frequently: approximately once a year for operational plants and every 2 years for preoperational plants. As far as results are concerned, about the same percentage of facilities have been out of compliance when inspected: 34 percent in both FY 1975 and 1976, and 29 percent in FY 1974.

FEDERAL PROGRAMS

AEC/ERDA

ERDA has two programs for monitoring in and near nuclear reactors: the Aerial Radiological Monitoring System (ARMS), which conducts general surveys, and its Regional Offices' inspections to check on contractors' monitoring procedures and data.

1. ARMS

The ARMS has developed considerably over the last 3 fiscal years, in budget, equipment and purpose. In FY 1974, only $600,000 was spent; in the next 2 years, the estimates were $850,000 and $1,300,000. The best part of the increase was for equipment, a modular survey outfit with gamma ray and infrared detection systems and special provisions for data acquisition and reduction, all of which could be transported and operated from helicopters in an emergency. Basically, the ARMS consists of two airplanes, crew, equipment, and operational and administrative support. ERDA hopes to build a simultaneous East and West Coast operation by 1979 and to improve its data collection and reporting systems.

The original orientation of ARMS was entirely to accident situation: planes could enter areas that might be too hazardous for ground vehicles, and they could assess the situation quickly, flying samples back to laboratories for additional analysis. The few routine surveys conducted by ARMS were done solely to provide background information to compare to accident readings. Now, ERDA plans a major survey of every important site each 3 years, in addition to less extensive annual surveys to help local operations. In 1975, 14 surveys were conducted.

Aside from gathering background data, ARMS is now credited with helping ERDA assess the environmental impact of its facilities. Once it actually did unearth some high activity which had escaped being noticed by licensee, state and EPA monitoring.

2. Inspections to check on procedures and data

ERDA contractors are responsible for conducting effluent and environmental monitoring in and near the nuclear reactors they operate, and for submitting the result of their monitoring to ERDA to show compliance with radiation protection standards. Since 1974, the data has been compiled and published annually; the most recent volume is "Environmental Monitoring at Major U.S. ERDA Contractor Sites, 1975." The report details how many samples of which media are taken, how frequently they are analyzed and the results, as well as descriptions of the site, weather conditions and more.

NRC's licensees conduct and report on similar monitoring, and the Commission inspects the licensees' monitoring methods and results; the inspection function has its own budget, with centralized records of how many inspections have been conducted where. ERDA's Regional Offices are responsible for the same kind of inspection of their contractors' facilities, but information on the extent of the program and budget is not presented in Congressional hearings or centralized in any way. Washington headquarters has no record of how many inspections its Regional Offices are conducting at contractors' reactors, nor of how many employees are involved in them. This information can be obtained only by Washington's contacting each Regional Office. Moreover, there is no way to isolate how much ERDA is spending either on monitoring done by the contractor, or on its own inspection and confirmation of the resulting data. Both are homogenized with operating budgets, for the reactors themselves and for the Regional Offices.

STATE VIEWS AND PROGRAMS

Each year the Bureau of Radiological Health compiles a Report of State and Local Radiological Health Programs, which provides detailed information on budget and personnel qualifications for environmental surveillance. Rather than duplicating their effort, this study gathered suggestions from States with reactors about changes they would like to see in their own and Federal monitoring programs. We also asked for limited financial data, including informmation on Federal contracts and funding--but our interest was primarily in gathering State officials' subjective impressions and ideas for change.

As background, the general picture in the most recent BRH Report (FY 1974) is that States are not using many of their resources for environmental monitoring: 118.8 person equivalents and $2,138,400 in all 50 States. There is no consistency among State programs in terms of legislation, the extent and nature of monitoring, or personnel levels and qualifications. Some States have extensive programs operating under very specific statutory authority with contracts from NRC to confirm licensee data, and agreements to furnish EPA with samples for the Environmental Radiation Ambient Monitoring System; other States have very limited programs with general "protecting public health" authority, and have little equipment, funding or personnel.

Although there are so many differences in scope and type of monitoring program among States with reactors--and they do not seem to correlate with any obvious variables (like the number of reactors)--the suggestions State officials made were remarkably similar. Many were interested in upgrading the qualifications of personnel as well as getting more money and people. Equipment is a big problem for many States, which cannot afford the major investment of keeping up with the latest technological developments. Some States mentioned that they would like to do more monitoring for specific radionuclides and to improve the system they have for confirming all licensee data. As far as the Federal role is concerned, States felt that more grant money should be available to them both for equipment and for operating expenses. Training programs and full exchange of information were also mentioned.

A few sample State programs are described in summary form below, to give a sense of the current situation. All data were furnished by the States themselves.

Florida

- conducts general monitoring and covers three reactors
- has 11 person-equivalents working with a State monitoring budget of $64,388 in FY 1976, an increase over the $57,949 available in FY 1975, and $45,958 in FY 1974
- works under general authority
- would like to include public drinking water supplies and specific monitoring for cesium-137
- receives no Federal funds
- considers its program inadequate and fragmented

Iowa

- conducts general monitoring
- has 2.5 person-equivalents working with a State monitoring budget of about $26,000 in FY 1976, compared to $23,000 available in FY 1975, and $20,000 in FY 1974
- works under general authority
- would like to update obsolete equipment
- receives no Federal funds
- considers its program inadequate

Minnesota

- conducts general monitoring
- had 5 full-time positions allotted in FY 1975, with a State budget of $102,225 for environmental surveillance compared to $100,925 in previous years. FY 1976 was not available, but it was noted that the program "has been severely cut since January 1976."
- works under general authority
- receives no Federal funds
- considers its program inadequate

Nebraska

- covers two reactors
- used 1 person-year for the last 3 years, with a total radiation protection budget of $84,650 in FY 1976, compared to $90,390 and $86,070 in the 2 previous years
- works under the Nebraska Radiation Control Act of 1963
- received two contracts from NRC in FY 1976, amounting to $12,400
- considers its program inadequate

North Carolina

- conducts general monitoring plus two power reactors and one research reactor
- has 5.5 person-equivalvets with a total environmental surveillance budget of about $187,500 in FY 1976, compared to $164,000 and $161,000 previously
- works under specific Department of Human Resources authority
- would like to do more independent surveillance around nuclear reactors
- has received about 25 percent Federal funding for the last 3 years
- considers its program inadequate

Oregon

- conducts general monitoring and one reactor
- had 3.5 person-equivalents in FY 1974, with a State environmental surveillance budget of $90,165 in FY 1976, as opposed to $81,521 and $64,662 previously
- works under specific statutory authority
- receives no Federal funding
- considers its program adequate within technical limits of the present state-of-the-art

South Carolina

- covers monitoring of 4 reactor sites
- had 6 full-time positions allotted for environmental surveillance personnel in FY 1976, an increase over the 5 allotted before
- works under the Atomic Energy and Radiation Control Act of 1967
- would like to include specific monitoring for krypton, iodine-129, carbon-14 and others around the Barnwell plant
- has an NRC contract to confirm licensee results
- considers its programs adequate

ARE STATE AND FEDERAL AGENCIES MEETING TODAY's CHALLENGES?--PART II

Terry R. Lash, Ph.D.
Natural Resources Defense Council, Inc.
Palo Alto, California

The complex problems posed by a large commercial nuclear power industry, especially the problem of disposal of radioactive wastes, are some of the more serious facing our society today. Resolution of these important nuclear issues involves much more than simply making technical judgments. The significant questions have important political, social, and ethical components that are not adequately addressed solely by scientific "experts" and technical bureaucrats. Nuclear issues generally, and waste management issues in particular, can and should be decided by the public through its broadly-based representative institutions.

The issue of how to ensure virtually perpetual containment of radioactive waste is fundamental to decision-making on the future development of nuclear power. As the country prepares to turn to nuclear reactors for more of its energy requirements, there is reason for concern that it may be tragically short-sighted to generate irrevocably large amounts of new wastes now on the optimistic assumption that a solution to the threats posed will be found in the future.

We are quickly losing the opportunity to plan rationally for the handling and storage of the radioactive wastes that are being produced at an increasing pace. Further major development of nuclear power should not be permitted to occur until there is a better understanding of waste disposal issues and there is a strong waste management program that is widely recognized as adequate.

Significant wastes, in terms of potential hazards to the environment and public health and safety, are produced at several points in the nuclear fuel cycle; e.g., during the milling of uranium ore, the operation of nuclear power plants, the reprocessing of spent fuel and the fabrication of fuel containing plutonium. There are three categories of waste--at both ends and the middle of the fuel cycle--that I will discuss today in the context of whether State and Federal agencies are meeting today's challenges. These are the high-level wastes, uranium mill tailings, and low-level wastes.

HIGH-LEVEL WASTES

The high-level waste materials certainly pose the greatest short-term potential environmental health hazards because of their emission of intense radiation and high toxicity in minute amounts. Furthermore, because the transuranic components of the wastes characteristically have long half-lives (i.e., long toxic periods), the general consensus is that the high-level wastes must be contained for the hundreds of thousands of years required for their radioactivity to decay to innocuous levels. To rely on active human surveillance and management to ensure their virtually complete containment over the toxic lives of the transuranic component of the wates is folly. Thus, the emphasis at the Federal level, with perhaps a few exceptions, has been on finding a suitable geological formation and site in which to "bury" the high-level wastes in a way that would not require continual human maintenance or surveillance to ensure long-term safety.

Until recently, governmental planning was premised on the assumption that irradiated ("spent") fuel from commercial reactors would be chemically treated ("reprocessed") to extract residual fissionable isotopes of plutonium and uranium. The expectation that a commercial reprocessing industry would develop may turn out to be completely wrong. The Carter Administration's recognition of the serious dangers posed by reprocessing and the "plutonium economy" hopefully means that this country, and eventually the world, will seriously seek not only to limit future reliance on nuclear power, but also to eliminate nuclear power as a long-term energy source. The main implication of these developments for waste management is that the high-level wastes will now be in the form of spent fuel, instead of solids from reprocessing plants.

Unfortunately, even though during the last 3 years we in the environmental community argued long and loud it should do so, ERDA failed to plan for the contingency that there would be no commercial reprocessing or that there might be a long delay in its initiation. In consequence, in the recent words of the Nuclear Regulatory Commission, "detailed analyses of the technology of spent-fuel disposal are not to be found in the literature." ERDA is only now re-orienting its research program to determine the potentially unique hazards associated with disposal of spent fuel.

Even though the question of what to do with the highly toxic radioactive wastes is consistently described as a major concern about the advisability of using nuclear power plants to produce electricity, the Federal Government, which has primary responsibility for developing safe nuclear power, has not yet demonstrated a means for permanently and safely storing radioactive wastes. More importantly, the Federal bureaucracy is not even adequately planning for the storage and disposal of radioactive wastes from the commerical sector and has not adequately alerted the public to the relevant issues. To date, the new Energy Research and Development Administration's radioactive waste management program can be characterized as fundamentally deficient and inadequate. (**Note added in proof:** The new Department of Energy, which assumed waste management responsibilities on October 1, 1977, has not significantly modified ERDA's former program.) Unless the Federal Government changes its current ways by showing a determination to break away from the narrow techinical approach that was characteristic of the defunct AEC's waste management program and to devote substantially increased resources to finding a solution, an adequately safe means for waste disposal will not be developed in a time frame fully consistent with protection of the public health and environment. The absence of careful planning of the Federal Government and the nuclear power industry may result either in the premature shutting down of nuclear power plants or in the unsafe storage of radioactive wastes.

In my view, there are essentially two possible explanations for the current lack of an adequate means or plan for the disposal of radioactive wastes. Either the Federal bureaucracy is to a large degree incompetent, or the radioactive waste disposal problem is considerably more difficult than has been publicly admitted by the nuclear power industry. My judgment is that a careful examination of the record reveals substantial support for both explanations.

The search for the "ultimate" solution to the problem of perpetually storing high-level radioactive wastes began shortly after passage of the Atomic Energy act of 1954. From the outset, advisors to the Atomic Energy Commission focused on bedded salt deposits as the most likely geological formation in which to dispose of the long-lived wastes. In 1957, for instance, a special committee of the National Academy of Sciences-National Research Council agreed that "disposal in salt is the most promising method for the near future."

However, during the late 1950's and early 1960's the Federal Government was actively promoting the "commercialization" of fuel cycle operations, including reprocessing and waste management. One of the criteria used by the AEC to judge proposals for transfer of reprocessing technology was private responsibility for the long-term management of high-level wastes. The AEC apparently explicitly stated that it did not want to receive high-level wastes for permanent storage. Because the original owners of the first commercial reprocessing plant at West Valley, New York, did not want to accept long-term responsibility for the wastes, the State of New York agreed to provide waste management services--expected to be near-surface tank storage--at the West Valley site in perpetuity.

As is well known now, this initial failure of the AEC to address the waste disposal issue comprehensively has resulted in an unfortunate situation at West Valley. There is not now a capability to remove the sludges from the storage tank, even though it is recognized that the tank has a useful lifetime of at most a few more decades. To correct this serious problem will require the expenditure of large sums of money that will have to be made available from the taxpayers of New york and/or the nation. Furthermore, there will probably be significant risks and hazards associated with disposal of the wastes, when a means is finally selected for that disposal. The West Valley situation is a classic case of bureaucratic shortsightedness and ineptitude.

During the 1960's after several years of investigation and study on bedded salt, the AEC selected an abandoned salt mine near Lyons, Kansas, as the location for a pilot repository for solid high-level and transuranic wastes. The repository would have been a Federal facility because an AEC regulation, which became effective in February 1971, required Federal custodianship of high-level radioactive wastes. Perhaps this new regulation was adopted because of the problems at the West Valley site. In any event, if the tests verified the Government's predictions of safety, the Lyons mine was supposed to become the first national repository for high-level radioactive wastes. For a number of reasons, however, the AEC formally killed its proposal for the Lyons salt mine on May 18, 1972.

In place of the Kansas repository, an AEC announcement called for construction of an engineered facility near the surface of the earth to store the wastes for an indeterminate period of time, while the prolonged search continued for an acceptable, safe geological site (including in formations other than bedded salt). In other words, the AEC was admitting that it was almost right back at square one in the process of finding a solution to the problem of ultimate disposal. No matter how historians judge this turnabout, it is likely that with reasonable planning the situation could have been avoided. Either the AEC did not adequately judge the safety problems with the Lyons site, which seems to be the case, or, at least, in the opinion of some who were involved, the AEC failed to appreciate the socio-political aspects of creating and storing radioactive wastes that are potentially hazardous for thousands of future human generations. In either event, there was a major failure in leadership at the Federal level.

Between May 1972 and now, the Federal Government's policy on the storage and disposal of high-level wastes has become even more uncertain and promises to remain so for months to come. In September 1974, the AEC issued a draft environmental impact statement under the National Environmental Policy Act on its suggestion to build some sort of containers (to be located at the so-called Retrievable Surface Storage Facility or RSSF) for "interim" storage of high-level wastes. The draft statement was severely criticized as being inadequate for decision making purposes by virtually all independent reviewers. This is a fatal deficiency because, in fact, the principal purpose of NEPA statements is the improvement of Federal decision making in order to protect the environment. Furthermore, many commentators observed that the AEC had improperly shifted the emphasis of the Federal waste management program from ultimate disposal to interim storage of high-level wastes. For instance, the U.S. Environmental Protection Agency, which rated the statement "Inadequate" (its lowest rating), said:

> "In our opinion, and as evidenced by the degree of engineering detail and refinement presented for the RSSF concept, the AEC has reversed the importance of the overall program (with its primary goal being the development of an ultimate disposal method) and the decision to construct a centralized Retrievable Surface Storage Facility (RSSF) (only one of the several feasible interim storage methods). In light of this situation, we feel that the AEC's waste management program, as reflected in this draft statement, has not adequately addressed the high-level waste disposal problem."

Many viewers, including NRDC, feared that the AEC's temporizing could too easily lead to the permanent storage of the wastes in the RSSF -- a possible approach that had been rejected earlier as inadequately safe. In light of these strong criticisms, the cancellation or delay of many nuclear power plants, and the failure of a commercial reprocessing industry to develop, in April 1975 ERDA abandoned the RSSF concept as the mainstay of the waste management program.

Since dropping the RSSF concept as the principal component of the waste management program, ERDA's efforts have bogged down. First, hydrogeological difficulties were encountered during exploratory drilling near Carlsbad, New Mexico. After a new, nearby site was selected for study, questions of conflicting resource use between the proposed repository and phosphate deposits were raised again. This issue is being restudied and the fate of the proposed facility is uncertain.

In February 1976, ERDA announced a major increase in its effort to establish a geological repository for commercial high-level wastes. But rather than leading to an acceptable solution to the problem, the proposed expanded exploration effort has principally crystallized State and local opposition to such plans. Communities overwhelmingly have passed referenda calling for abandonment of exploration plans, and States are passing legislation to restrict or prohibit outright ERDA's consideration of those States as potential sites for a waste repository. **(Note added in proof:** Evidently because of rapidly changing policies, the contractor (Union Carbide) administering ERDA's expanded program has decided to withdraw early in 1978. As of December 1977, no substitute arrangements have been announced.)

In April of this year the President announced that his assistant for energy will direct a task force to review the entire ERDA waste management program. The outcome of this latest review is uncertain. **(Note added in proof:** As of December 1977, the Presidential review has not been initiated.)

In the 2 years since ERDA de-emphasized temporary surface storage for commercial high-level wastes and substantially increased the size of its geological disposal program, new studies have concluded that the Government's waste management program has been and, to a significant extent, continues to be inadequate. For instance, an appendix to the so-called Fri Report, which was submitted to former President Ford in September 1976, states that:

> "The Federal record in nuclear waste management is not outstanding. Comprehensive research and development of waste disposal technology began only recently, but is not a high priority. . . . Nuclear waste management, historically, has been plagued with failure to demonstrate acceptability as safe, societally responsible, or environmentally sound. Licensing and environmental impact statements are necessary, but not sufficient to ensure public acceptability . . . . Convincing localities to accept nuclear waste repositories will require reversal of past shortcomings in local relations and probably, development of new incentives. Public acceptability could become the central issue in acceptance of foreign nuclear waste."

On July 21, 1976, the U.S. Court of Appeals for the District of Columbia Circuit found in Natural Resources Defense Council, et al. v. NRC, Nos. 74-1385 and 74-1586, ("Vermont Yankee") found that the development of facts on waste disposal and reprocessing during licensing proceedings was inadequate. In response, the NRC established a special Task Force to review the existing literature on disposal of radioactive wastes and to prepare a report based on that review.

The Task Force Report found that:

> "Two themes run through the history of the nation's development of a waste management policy. The first, still widely prevalent, is that technological expertise is alone sufficient to solve the waste management problem. The second is that the consideration of nontechnological problems is not only irrelevant, but in many cases is actually a hindrance to technological progress. There seems to have been an underlying belief that a waste management system would be self-implementing or automatically implemented when needed."

But Marcus Rowden, Chairman of the Nuclear Regulatory Commission, testified before the Joint Committee on Atomic Energy on May 12, 1976, that:

> "Among the ingredients for the safe management of nuclear wastes, two that stand out are a trust-worthy technology and a process for the timely implementation of that technology . . . . Having the technology on the shelf is not enough . . . . Organizations must carry out the tasks."

That is, contrary to the "underlying belief" of the Government's waste managers, the technology for safely storing and disposing of radioactive wastes is not "self-implementing or automatically implemented when needed. " Thus, even if an adequate technology for safely managing wastes existed, the Government's program is insufficient to assure that the technology would be used effectively.

The Task Force Report issued following the Vermont Yankee decision also pointed out in the following restrained language that there are significant uncertainties about how satisfactory geological disposal of high-level waste will be:

> "Past work does not, however, fully cover the risk situations that should be explored. Representative studies have been done with varying degrees of depth and sophistication, but there are still uncertainties in areas such as the effect of waste presence on repository stability; the probabilities and consequences of intrusive acts by humans; the validity of data used in modeling studies; the design and regulatory actions needed to minimize possibilities of repository failure; projection of future societal habits and demography, and, finally, the relative importance of various potential initiating events.
>
> "These uncertainties have permitted considerable controversy concerning the long-term risks and impacts of disposal of radioactive wastes."

This same point about technology not being self-implementing was emphasized by a different NRC Task Force involved in reviewing the waste disposal problem. In its draft statement on goals and objectives for waste management, which was discussed at a Government-sponsored symposium in October 1976, the Task Force stated that:

> "Past claims by officials and by members of the nuclear community that the problem has been--or readily can be--solved have rested on what we believe to be a narrow, purely technological, understanding of the problem."

More recently, an excellent major report on the Government's waste management program, prepared for ERDA by Mason Willrich, a supporter of nuclear power, concluded as follows:

> "The existing organization for radioactive waste management is likely to be unworkable if left unchanged."

* * * * *

> "The existing framework for radioactive waste regulation is likely to be ineffective if left unchanged."

Significantly, these conclusions are supported by Professors Norman C. Rasmussen and David J. Rose, two well-known proponents of nuclear power in MIT's Nuclear Engineering Department.

If the record of planning for the storage of, and in the case of West Valley actually storing, commercially-generated high-level wastes raises serious questions about the capability of the Federal Government to resolve the waste disposal problem satisfactorily, so does the experience with the handling of the government's radioactive wastes to date. The history of waste management at the nation's principal storage site, the Hanford, Washington, Reservation, which is now managed by DOE, is disquieting, to put it mildly. Because of previous bad decisions and wholly inadequate planning for the future, the Government has been forced into seeking emergency appropriations in order to minimize the continued leakage of high-level radioactive wastes into the soil at the Hanford Reservation. Already there have been over 20 accidental releases of high-level liquid wastes from tanks and connecting pipes, totaling about 500,000 gallons, including one leak that went undetected for 50 days because of nonperformance of duties and poor administration. More leaks are expected in coming years, even though there will be an increased effort to prevent them. The long-term effects of past and future leaks are virtually unknown. All that can be said is that the wastes are getting out of control.

The storage and disposal of radioactive wastes on the Hanford Reservation is, in my opinion, a national disgrace. Although 75 percent (by volume) of the accumulated high-level radioactive wastes in the country are located at Hanford, and the Government's program has been in existence for 30 years, there is not yet an acceptable long-term means available to store these wastes safely. Indeed, lawyers for the Government recently argued in court that a plan or proposal for the disposal of Hanford wastes does not exist.

In summary, in the past, the Federal Government has not even come close to meeting its responsibility to ensure long-term protection of the public from the hazards of radioactive wastes. This failure continues today with only small improvements. The Federal Government certainly is not meeting today's challenge to dispose of high-level radioactive wastes.

Frankly, I do not know whether an acceptably safe waste disposal scheme can be identified and implemented. Although there are significant uncertainties about our ability to dispose of wastes safely, I am unaware of any reputable scientific study that concludes it cannot be done in principle. In fact, some qualified outside reviewers are convinced that safe disposal can be accomplished if the technology is used properly and expeditiously. The main lesson to derive from the history of radioactive waste management, however, is that under the existing institutional arrangements, the best technology will not be used on a timely basis. The failure in the 1960's to use the then-existing technology to solidify high-level liquid wastes at the commercial reprocessing plant at West Valley, New York, and at the Government's reprocessing plants on the Hanford Reservation are perhaps the most striking examples of the nuclear establishment's willingness to minimize current costs and responsibilities at the risk of increasing long-term costs and hazards. This failure to solidify wastes properly will result in an additional general tax burden of hundreds of millions of dollars in the case of West Valley, and perhaps tens of billions of dollars in the case of the Government's own wastes.

The new Program for Commercial Waste Management that was announced in 1976 is not a better program; it is only a bigger program. To date, the new program has not made significant progress toward resolution of the waste disposal problem. In fact, in some respects, the program has retrogressed. Citizens in States where exploration of waste disposal sites has been announced perceive, correctly I believe, that ERDA's program is inadequate. As a result, citizen and State governmental opposition to disposal of wastes in these States has increased and stiffened considerably. This high level of antagonism and turmoil is unnecessary and counter-productive.

My suggestion is that administration of the Government's waste management programs be reorganized. Both the Willrich Report and the excellent Report by the British Royal Commission on Environmental Pollution have recommended that new organizations be created to manage radioactive wastes. There is much merit in that recommendation. However, I urge caution in establishing a new, mammoth bureaucracy pending wider consideration of its implications. In particular, I am concerned about how the public corporation recommended in the Willrich Report will be accountable and responsible to political institutions and the public, and how an adequate degree of coordination between the corporation's operational needs and the Government's research and development activities will be achieved.

More generally, we should not create an organization that will be difficult to change, because we undoubtedly will make mistakes initially. The new organization must be planned to detect errors and correct them as an integral part of its overall functions. This consideration precludes creation of a large public corporation until there is a better understanding of the nontechnical aspects of waste management and a generally accepted means for disposing of wastes.

The Administration has announced a review of the waste management program. I hope that an immediate outcome of that review will be the placement of waste management responsibilities in the Office of the Secretary of Energy, in order to ensure high-level attention to the problem and proper coordination of activities. An important aspect of such centralization would be to place radioactive waste management policy making more directly in the hands of an official who can take a broader perspective of the issue than the AEC and ERDA and who, hopefully, will not assume, as the AEC and ERDA have done in the past, that technologies are self-implementing. In conjunction with this reorganization, there should be a major attempt to increase confidence in the operational parts of waste management programs by establishing mechanisms for meaningful public input and complying with the letter and spirit of the licensing requirements of the Energy Reorganization Act of 1974. Citizens should have easy and complete access to reports, studies, and other documents prepared by the Government and its contractors. Citizen committees should be created to ensure a clear exchange of ideas with Government officials. And citizen participation in regulatory proceedings should be facilitated by government assistance.

Furthermore, both the new Department of Energy and NRC should be fully candid about the technical uncertainties surrounding waste management operations. Recently, an astute student of nuclear matters stated that it was his belief that "...public acceptance, as distinguished from legal, technical, or marketing acceptance, will not be forthcoming until we admit that the problem is potentially serious enough to disallow further waste generation until such time as we verify our engineering theory." I fully concur. The agencies must sincerely admit that a conceivable result of regulatory proceedings is the conclusion that radioactive wastes cannot be handled safely enough and that no more wastes should be created.

The States are more directly involved in the management of two other types of wastes--uranium mill tailings and low-level waste--that have not been safely disposed of in the past and for which existing programs are inadequate.

MILL TAILINGS

Once mined, uranium ore is transported to mills which crush, grind, and chemically process it to produce a semi-refined compound (U_3O_8) known as "yellow cake." The spent ore is discharged in the form of a finely ground slurry, the "tailings," to a settling pond where the water gradually dissipates through seepage and evaporation. The residue is a sand-like pile containing, for instance, the particularly hazardous long-lived natural radionuclides thorium-230 and radium-226. Because of the long-lived components of mill tailings, these wastes, by some assessments, will be potentially more hazardous than the high-level wastes 1,000 years from now.

Unless the tailings piles are properly stabilized, dangerous amounts of radium can be leached into surface or underground waters. Furthermore, radioactive dust particles can be blown long distances by the wind. These dispersal mechanisms must be prevented from distributing the large amounts of radioactivity in the tailings piles for tens of thousands of years. Even by the NRC's own admission, current stabilitzation techniques are wholly inadequate to measure up to this technically difficult task.

The magnitude of the total human illness and death that potentially could be caused by the release of natural radioactivity from poorly stablilized tailings piles is uncertain. One scientist, however, has recently estimated that the radon gas alone, escaping from tailings piles, could cause as many or more deaths (from lung cancer) per unit of electricity as polluting coal-fired power plants.

While the NRC has taken some steps to determine how best to store the tailings permanently, currently there is no assurance that the mill operators, instead of the taxpayers, will be forced to pay what promises to be a large bill for safe disposal of the tailings. In order to prevent the taxpayers from being struck with the cost of cleaning up these hazardous wastes later, as has already happened in Grand Junction, Colorado, and as probably will happen in Salt Lake City, Utah, the Natural Resources Defense Council petitioned NRC last March to adopt a regulation forcing mill operators to post a performance bond ensuring safe permanent storage of the tailings at the industry's expense, when a means for disposal is finally selected by NRC. We are very pleased that the states of Colorado, Utah, New Mexico, Texas, and Montana have generally endorsed our petition before the NRC.

In response to our petition the NRC is conducting a major review of its regulatory program on uranium milling and preparing a generic environmental impact statement on the hazards posed by milling and disposal of tailings. We are hopeful that at the end of this analysis the NRC will make major improvements in its regulatory program to assure full consistency between Federal and State programs and protection of the public health and safety. The failure of the NRC to adopt better interim regulations during the extended review period (from March 1975 to the end of 1978) is bitterly disappointing, however.

More recently, lawyers representing NRDC have filed a lawsuit to ensure that all uranium mills, including those licensed by State goverments under the Agreement State Program, are built and operated only after an effective environmental review of proposals are completed, as required by the National Environmental Policy Act (NEPA). Current practice allows Agreement States that do not have a State equivalent of NEPA to issue mill licenses without first preparing environmental impact statements. We firmly believe that either the NRC must prepare EIS's in such cases, or the NRC must require the States to conduct the NEPA review according to well-established Federal standards. In the latter case, it would be appropriate for the NRC to provide the necessary resources to the States so that they could conduct an adequate NEPA review.

LOW-LEVEL WASTES

In the past, low-level radioactive wastes received for burial in shallow earthen trenches in 6 States were generated at hospitals, research facilities, and industries using radioisotopes. In the future, however, the low-level wastes will be produced predominantly by the nuclear power industry. These nuclear power wastes will contain large quantities of plutonium-239 and other long-lived, extremely toxic radionuclides, if reprocessing and plutonium recycle are permitted in the future. Indeed, some calculations show that the amounts of plutonium, one of the more toxic materials known to man, in the low-level wastes are comparable to or even greater than the amounts in the high-level wastes. Since the low-level wastes are buried under conditions much less safe (e.g., shallower depth of burial and lower integrity of containers) than those that will likely pertain to high-level waste burial facilities, there is reason for grave concern over the long-term safety of these facilites.

The most recent study on low-level wastes completed by the U.S. Environmental Protection Agency concluded that the West Valley site had failed to meet the major goal of "containment and confinement of the wastes for the duration of its hazardous lifetime." Although the EPA study failed to pinpoint the exact sources permitting the release of radionuclides, it identified three potential major pathways of movement at West Valley. In order of importance these were (1) surface water transport resulting from the runoff of seepage contaminated water through the burial trench caps, (2) surface water transport resulting from discharge of treated trench water into nearby streams, and (3) subsurface migration of contaminants through geological formations.

Similarly, an EPA study for the Maxey Flats site determined that plutonium contamination "exists in and around the Maxey Flats burial site," that plutonium "has migrated or moved from the trenchs," and that "other radioactive contaminants are moving or migrating also." Although the nuclear industry representatives take issue with the methodology used by EPA's hydrologist in evaluating the situation at Maxey Flats, and point to ERDA's critique of EPA's analysis as supporting their contentions, the fact remains that EPA, after reviewing ERDA's comments, adopted the basic conclusions of the earlier study as valid.

While exact pathways followed by the migrating radioactive material have not been determined yet, the West Valley and Maxey Flats experiences make it clear that current disposal techniques cannot be counted on to contain low-level radioactive wastes. On the current record, it is impossible to predict whether, and to what extent, such movement of potentially hazardous material could again occur. In the absence of more substantial scientific knowledge, the only viable option to insure protection of the public health and safety is to discontinue the current unsatisfactory disposal practices, and to adopt interim storage techniques which will achieve absolute containment until further analysis can be done to determine what degree of containment is essential and what long-term storage methods will best provide that level of containment.

NRDC has petitioned the NRC to improve its regulation of low-level waste burial grounds. In response, NRC is reviewing its program, and plans to issue an environmental impact statement that considers the cumulative effects of current and alternative waste disposal practices and policies. A recent NRC Task Force Report on low-level wastes makes several excellent suggestions for upgrading the current regulatory program. However, to date the Commission has failed to act positively on either the regulatory aspects of NRDC's petition or the recommendations of its Task Force. Further delay in improving protection of the public health and safety through better interim regulations is unwarranted.

THE HUMAN FACTOR

Before concluding, I want to reflect on what poses the greatest uncertainty and hazard in the handling of radioactive waste: the human factor. As the historical record shows, human fallibility can result in poor radioactive waste management policy and in the failure to design, site, and construct a waste repository properly. Or, once a repository is in place, human error or irrational human behavior could lead to the release of large quantities of radioactive waste. The recent careless handling of radioactive liquid wastes at the Hanford Reservation, resulting in the release of 115,000 gallons during a 50-day period, is indicative of the type of human error that will have to be guarded against for centuries into the future. And, one does not have to be a psychoanalyst to realize that some people have deep-seated irrational tendencies to hostility and violence; there are examples of such behavior reported in the newspapers almost every day.

One group of scientists, working under contract for the former Atomic Energy Commission, tried to evaluate the overall risk posed by radioactive waste management systems. One of their important findings is that "human error is a contributing cause of many component faults (in fault tree analysis)." These scientists also found that:

> "More important is the possibility of deliberate human acts for purposes of diverting nuclear materials or of destruction of containment/confinement systems. Such human factors, especially the last mentioned, are difficult to quantify because the probabilities depend on the attitudes of the individual person and of the population at the particular time. In those attitudes are reflected many sociological variables which are highly unpredictable."

Alvin M. Weinberg, the former Director of the Oak Ridge National Laboratory and now Director of The Institute for Energy Analysis, has eloquently addressed the social constraints that would be necessary to impose on society, if we choose to have a large nuclear power industry:

> "No matter how good fission technology becomes, there undoubtedly will remain possible dangers that can be avoided only through intelligent, long-term intervention. Perhaps the most pervasive of these human interventions is the necessity for a long-term social commitment simply because ^{239}Pu has such a long half-life....Beyond this is a commitment to expertise of a very high order--again a commitment that will last for many, many generations. What can we do to ensure the longevity and viability of the

social mechanisms that seem to be required if we concede that we shall always be dealing with the high amounts of ^{239}Pu?"

And there, in my opinion, lies the fundamental problem with perpetually trying to safeguard large quantities of radioactive wastes: what degree of infallibility of people and stabiity of our societal institutions will there be during the next one million years?

DISCUSSION

MR. SIMMONS: Dr. Sloan, what would you think about a national repository where information on therapy doses would be assembled? Would this be helpful in a data collection system for future reference from a latent effect?

DR. SLOAN: I am not quite sure of the sense that you mean that. I am not quite sure what kind of repository you had in mind. Certainly radiation therapists know the approximate range of dosage they give for different purposes.

MR. SIMMONS: Well, specifically, every physician has to keep a record of the dose that he administers to a patient. They have to keep that record--for 5 years it is in that hospital. I do not know what they have to do personally, and I am thinking of latent effects from radiation treatments. I think if we had a national repository of every dose given in the country we would have a lot of information that we could use in later years. In other words, we could rectify lots of our situations in radiation treatments, perhaps.

DR. SLOAN: Well, I think it would be a splendid thing if from now on hospital records and private physicians' records of radiation administered to each individual patient were retained. Many hospitals have discarded all records older than 10 years. And with something of this sort, I think we could insist that radiation records be retained indefinitely. Consideration has been given to having each individual have his own radiation history that he retains himself, and maybe that is a way of doing it. I think it is very difficult to set up a system that would reflect the irradiation given in private radiologists' offices at the present time in the United States.

There are many logistical problems in what you propose. Ideally, I think everyone should have a record of every irradiation exposure he has ever had in all his life and have it for the rest of his days, but I think that is very difficult.

DR. SLOAN: Could I make just one comment in response to Mr. Alverez's accusation of a very cozy relationship between the American Cancer Society and the American Cancer Institute? I know what he has been reading, but I would like to assure him that in the National Cancer Act, the Cancer Institute was told, was directed, was authorized, to work very closely with all national professional and voluntary health agencies to make sure that it did not duplicate efforts already in progress and that it worked with maximum cooperation with them. I think one could look at the relationship of the National Cancer Institute of the American Cancer Society in another way as saying this is a splendid example of the kind of cooperation that should take place.

MR. SHAVER: I have a question for Dr. Sloan. You alluded to the "60 Minutes" show in January. If they were to decide to do another story on this problem, would you expect the results that they showed in the January show to be different; and if so, would you encourage "60 Minutes" to prepare a sequel?

DR. SLOAN: We would have been a little happier if the "60 Minutes" show had not been rather accusatory in its attitude; indicating that the treatments that were given in that period of 1925 to 1955 were done because physicians at that time believed that was the very best medical practice they could deliver. So, I would love to see them correct that a little bit. I think we could do another program that might be of service in trying to indicate to individuals how they can make contact with physicians or hospitals and the kind of responsibility each individual really has to assume himself because of the real impossibility of connecting records to people at this late period.

And, so, we would welcome another show by "60 Minutes." It did have a tremendous response to that one.

MR. SHAVER: Would it be in accord for NCI to actually recommend, or encourage, or seek out the "60 Minutes" staff and confront them with this?

DR. SLOAN: Well, we might do that. The next thing we have on our agenda at the moment is a press briefing in mid-July in which we are going to be discussing with the press and the media the public education part of our program. We think we have done all we can on the professional level. We have certainly made the information we think physicians should have as widely available to them as we can.

Now, we are about to start a distribution of rather catchy leaflets through such outlets as supermarkets and other places where the public may be able to pick them up. We will give that very careful thought as to whether we should ask "60 Minutes" if they would like to do another program.

MR. SHAVER: I have a question for Mr. Alvarez. I would like to congratulate him on a very stimulating talk. I think most of the talks I have heard throughout the week have been less controversial than his, and I think it is nice that we have some stimulation provided for the group. It would seem that one of the challenges you admitted yourself, you admitted being a layman on radiation protection, and I guess I would not take issue with that.

It would seem that EPA has done an excellent job in explaining to the Environmental Policy Center their particular problems. It would seem that the other agencies have the job to do to get their information in front of you in the same quality that EPA did. How would you suggest that this conference and the other agencies accomplish this?

MR. ALVAREZ: Well, I would suggest one thing. If NRC would return my phone calls, or ERDA, that may help. That would be a good start.

MR. SHAVER: Is there a way that we, this group, might utilize your organization hearing consumer positions and providing our positions, reactions on these problems?

MR. ALVAREZ: Well, I think that that is a very good idea. I think that at some later date that we should seriously think about sitting down and getting a forum together, especially the State programs with the public interest groups, because, as I said before, just the few days I was here I think I learned more about the nuts and bolts of what is going on just in the couple days than in the 4 or 5 years I have been in Washington. And the information that the States have to share with public interest groups is invaluable. How we go about doing this is going to require some money and it is going to require some time and planning, but I would certainly be glad to start discussing this with either you or anyone else that is interested and see if we can't work something like this out.

MR. SHAVER: For the past few years, I think we have heard recommendations that we shall get with your consumer groups, and that is an easy thing to say; but it is hard to make the penetration and identify who the appropriate groups are. As I understand your organization, you could probably act as a clearinghouse and maybe provide some impetus to get started.

MR. BAILEY: I would like to indicate that the proceedings of this conference for the 9 years now have been available each year. They are sold by the Superintendent of Documents and the National Technical Information Service. I think the discussions that have gone on each year are available to various groups that are interested.

MR. LACKER: I am sure this is true, but sometimes we do not know how to get to those things. I think really the things that we have participated in this week indicate that this conference is willing to meet the challenge of getting involved. Our Monday session was a good example, and I think that the session this afternoon is also.

MR. DAVIES: I would like to commend both Mr. Alvarez and Mr. Lash for a stimulating discussion. I do have a question for Mr. Lash. If you did comment concerning support for intervener groups in connection with hearings or nuclear fuel cycle power reactors, and so forth, do you personally feel that there is enough being done in terms of similar efforts by intervener groups with respect to fossil fuel cycling? Should more be done?

MR. LASH: I am not as familiar with interventions involving coal-fired power plants as with nuclear interventions, since I have not participated personally in any fossil fuel plant interventions. But I would suspect, nonetheless, that, yes; there needs to be greater assistance and a greater role for interventors in those cases. I think that citizens' groups are not strictly anti-nuclear and pro-fossil-fuel. There is quite a diversity of opinion; and certainly there is a lot of opposition to fossil fuel burning as it has taken place in the past and a very strong desire to see improvements made, if that was the gist of your comment.

REPORT ON RESOLUTIONS

J. Dale McHard
Chairman
Conference of Radiation Control Program Directors, Inc.

This is the closing session of the Ninth Annual Meeting, and the agenda calls for a report on resolutions. There will be no report on resolutions as none were received by the Board nor were any presented during the annual business meeting. However, your attention is drawn to the report on handling of resolutions by Sherwood Davies, a committee of one. Mr. Davies' recommendations were:

1. To amend the by-laws to provide a mechanism for formally handling resolutions;
2. Establish a Resolutions Committee appointed by the Executive Committee consisting of two or three members who will rotate; and
3. Define the functions of the Resolutions Committee to receive all resolutions submitted by the membership and the handling process of the resolutions in accordance with the by-laws.

Specifically, the Committee would review resolutions for consistency with the Constitution and by-laws as well as establish policies at the Conference.

EXECUTIVE BOARD REPORT

J. Dale McHard
Conference of Radiation Control Program Directors, Inc.

The Executive Board met numerous times during this Ninth Annual Meeting beginning on last Sunday morning. As usual, these meetings were hectic and were sometimes snatched from small bits of time lying around unused. I continue to be amazed at how much abuse the body is willing to take when pushed to the maximum. I believe this is the appropriate point to take note of the valuable work that Jerry Parker has contributed during his tenure as Chairman during the past year. His 7 years as Secretary-Treasurer of the Conference should also not be overlooked. Accordingly, on behalf of the Executive Board and the entire Conference membership, let me thank you, Jerry, for your efforts.

During the past 5 days, the Executive Board has met with each of the Federal sponsoring agencies as well as representatives of several other organizations. As a result of these meetings, the Board will take several steps to implement new programs, or to otherwise meet issues that have been identified. In meeting with representatives of the NRC, the thrust for discussion was in regard to emergency response planning. I might point out that in reviewing some of the previous proceedings, I notice that this is an ongoing subject. The Board plans to actively pursue this issue through the Conference Task Force on Emergency Response Planning and with the NRC directly.

The Board's meeting with EPA representatives was concerned with several issues and matters. The Board intends to continue its efforts to obtain the completion of guidelines, such as the PAG's and the soil contamination guide, so that the Conference and States may have such information as soon as possible.

The Board also met with representatives of the National Bureau of Standards to discuss matters related to the contract on radiation measurements and related issues. It appears that our work in meeting the commitments of this contract are progressing very well.

This afternoon, the Board met with BRH and EDRO representatives. Again, a large number of subjects were discussed including the Seattle meeting, as to its content and format; training and the modalities available to provide such; the x-ray compliance program and State contracts thereunder; and the issue of efficacy in x-ray usage.

The Board met with representatives of the American College of Radiology (ACR), and Mr. Parker and I also met with most of the ACR members that attended this annual meeting. Several major regions of mutual concern were discussed. Two of these are worthy of mention in this brief summary. One, the Monday session, including the 2-hour dialogue over wine and cheese, all of which were co-sponsored by the ACR and the Conference; and two, methods of improving communication between the two organizations. It should be noted that the first of these items, that is, the Monday session, was an obviously successful example of the second item, improving communications. The ACR has also suggested that a representative of the Conference be appointed to attend meetings of the ACR Committee on Unit Standards and Radiation Measurements. All of the issues identified will be pursued by the Board in the coming year.

The Board also met with representatives of the American Registry of Clinical Radiological Technologists (ARCRT), to identify and discuss areas of mutual interest and concern. Credentialing of x-ray technologists was one major subject of discussion. The Board will proceed with establishing closer relationships with ARCRT.

The Board met with a representative of OSHA. Again, our discussion centered around an exchange of information of mutual interest. The current status of and the future plans for the proposed OSHA ionizing radiation regulations were discussed among other topics. As a result of this meeting, the Board plans to initiate efforts to identify persons within the OSHA organization as contact points for the States and the Conference on issues confronting both the Conference and OSHA.

Finally, in the context of this meeting's theme, I believe that the coming year will be challenging for both the Conference and me as your new chairman. I accept this challenge and the responsibilities which you have given me by selecting me as chairman. From past experience, I believe that we can fully expect the Conference to meet its challenges. To do so, however, each member must be willing to do his or her part to go that extra mile, to put forth that extra effort which oftentimes is the small difference between success and failure.

SUMMATION AND CLOSING REMARKS

Sheldon A. Schwartz
Office of State Programs
Nuclear Regulatory Commission

Robertson J. Augustine, Ph.D.
Office of Radiation Programs
Environmental Protection Agency

James W. Miller, D.D.S.
Office of Medical Affairs
Bureau of Radiological Health, FDA

J. Dale McHard
Chairman
Conference of Radiation Control
Program Directors, Inc.

MR. SCHWARTZ: I would like to break my remarks into two areas. One, I would like to talk about a couple of studies that the Nuclear Regulatory Commission has ongoing right now in the Office of State Programs; and then some remarks I would like to make that maybe we can all think about on our way home.

One study I would like to mention is the study of Agreement States. Last October, the Nuclear Regulatory Commission's Office of State Programs began a critical assessment of the Agreement State Programs. As you know, there are 25 Agreement States, and we would like to have more Agreement States. These States regulate about 11,000 licenses. There are four basic questions that we are addressing in this study.

First, should the NRC vigorously encourage now States to become Agreement States; and what mechanism can we use or should we be using if we want to involve more States in the program? There are three options under this question that we have identified: (1) continue the present program of working with prospective States (and that is almost a status quo option); (2) provide development money and transfer funds to States who were working actively toward an agreement; and (3) provide partial direct operating funds to States for the operation of their agreement programs.

Second, should the NRC relinquish additional regulatory authority to the States; or, conversely, should NRC reassert authority in specific areas? We have had discussions about the low-level burial report during our meeting here in Seattle.

Third, what changes, if any, should be made in NRC's oversite role of the adequacy and compatibility of existing Agreement States?

And, lastly, what should the Commission's posture be regarding the question of exclusive Federal jurisdiction over radiation health and safety for source, byproduct, and special nuclear materials?

As most of you know, we have written to the governors and asked them these questions, and our responses are rolling in. The reason why I am mentioning this study is because we intend to have an early draft out sometime this summer, and working with our partners from the Conference, I think we would like to get some feedback as soon as possible.

As you know, bureaucrats are always studying; another study that we are involved in is a study for improving regulatory effectiveness in Federal/State siting actions. In September of last year, NRC's Office of State Programs undertook a study of means to improve the procedures for Federal and State participation in decisions concerning the siting of nuclear facilities with particular emphasis on methods for coordinating and reaching environmental decisions. During the study, we worked in close cooperation with many States and many individuals from many States through the National Governors Conference; specifically their Subcommittee on Energy chaired by Governor Bob Straub of the State of Oregon.

We held two workshops, one in Atlanta and one in Chicago, specifically to review the progress of the study and to bring as much involvement, in an early stage, of the States and interested parties. Additionally, there were two panels of experts that were convened; one to discuss and make recommendations on the need for power considerations, chaired by John Nassikas, the former chairman of the Federal Power Commission; and the other panel was what we call the efficiency or effectiveness panel, that was to define in some comprehensive, understandable way what the meaning of efficiency or effectiveness in the siting of nuclear facilities is. That one was chaired by Joel Haggard, an attorney from the State of Washington. The report is now complete. It is being mailed out to each State and to every individual whom we think would like to see this study, because we again want to get some feedback on what you all think.

I will briefly go through the five major recommendations in this study, so you can start thinking about it and whether you have any comments. The first recommendation was that Federal legislation authorize coordination and early and open planning by utilities and States or associations of States for all forms of electrical generation. Second, that NEPA be amended to allow Federal agencies to accept for inclusion in final environmental impact statements, environmental reviews performed by qualified States operating under Federal guidelines. Third, that States be authorized to certify sites for generating facilities. Fourth, that State certification of need for power and need for facility be final and binding on Federal agencies. Fifth and lastly, that coordination of the Federal and State regulatory actions be emphasized in order to minimize duplication and create a commonly available and publicly disclosed data base. Again, the reason I am telling you about this is because I think there is a lot of interest in this study.

I have been involved in the Conference for 3 years now. The first meeting I attended was in San Antonio. I think it has been a fruitful and rewarding experience for me and I hope you feel the same. I have seen an upgrading of the State programs and a reduction in what I think of as bickering and wasteful hardening of positions by providing a forum for all of us to discuss and resolve common issues. I have seen an increase in the awareness and acceptance on the part of those at the Nuclear Regulatory Commission that States have a legitimate role in NRC business and can provide thoughtful, positive and practical insight into solving our common regulatory problems.

Well, therefore, I guess everything is rosy; right? Wrong! In meeting yesterday's challenge, we have not adequately involved the public. We have been regulator talking to regulator and regulated. And we are all the beneficiary of these close working relationships. Our inheritance, therefore, is the lack of public trust in government decisions. I submit that a challenge we have been talking around is how do we restore public trust in government. We have, each of us individually and collectively, experienced legitimate pressure and legitimate concerns on the part of the public. Decisions that affect the public must provide for substantive public involvement early on, and not after the decision is made. And we are trying to legitimize that decision by, "getting public comment."

The current process, although getting better, cannot continue if we are going to have a stable regulatory process. So, what do we do? Well, there was a town meeting in Washington a couple weeks ago, and there was consensus on four aspects of how to regain public confidence in government decisions. The first is a **change of attitudes.** All of us have an ego problem and attitudinal blocks that cause us to ignore other opinions. As public employees, we cannot make private decisions that have public impact. Changing attitude means to me the internal awareness of myself and the internal awareness of the organization that the public interest must be satisfied as a **regular way of thinking** and not an extraordinary way of thinking. A business as usual approach.

Second, **increased public participation,** and in an early-on and meaningful type of participation. Each of us should look to ways to adapt our existing mechanisms for decision making to involve the public early on.

Thirdly, **get and retain competent people.** How? Some say it is money, but I think it is more than money, because I think money is what some of the management people call a treat and it is not an adequate motivational tool by itself in the long haul. I think responsibility, accomplishment, real acomplishment, true professional growth and ability; to have true professional growth is the thing that leads to the retention and the recruitment of competent individuals and leads, I believe, to public trust in government that we are all seeking.

And, lastly, **improved performance**; and I understand this Town Meeting identified this as the most important aspect. I visualize improving performance as (1) publicly announced schedules for decisions that cause those decisions to be made on schedule; (2) scrupulously assure that budgets are met and a product results from the expenditure of public funds; and (3) be honest. Bob Ryan talked a little bit about this in his opening remarks; do not get boxed into a corner because you will not admit you are wrong. We end up backing more turkeys this way, and it causes a drain on limited resources for frutiless projects that ultimately detract from our overall performance.

This is not a cookbook, but I think if we all make ourselves aware, we can restore the public trust which is, I believe, the profit motivation of a public agency.

I will get off my high horse now. I would like to personally thank Bob and Marian Will. It was a great meeting and you and your family really deserve a lot of credit for it.

Dave and Lucy Flora; thank you very much.

I would like to express my appreciation personally and also for the Agency, because I think it was a very good meeting. I think the year of Jerry Parker was a year of change. I see the Conference getting stronger, both technically and politically. And I think Dale, as beneficiary, will have a little better Conference because of Jerry.

And Alice Dolezal, congratulations. We are looking forward to working with you in the coming year.

Thank you for being so patient with me and sitting through my ramblings here today.

MR. AUGUSTINE: As we come to the close of another National Conference on Radiation Control, the 9th annual one, I would like to reflect for a moment on the theme of the Conference. That theme, of course, is "Meeting Today's Challenges." I think these words are very significant. If we look at each one of them, we might think about each one of them.

First, the word challenge. I think by having this in the theme we mean that there are still challenges in the field of radiation protection. We have not solved all the problems, obviously, nor are the problems so trivial that we do not consider them challenges. The word "today" indicates that we are not talking about our problems in the past, which hopefully we have been challenged by and met the challenge; we are not talking about our past accomplishments; we are not resting on our laurels; we are addressing our current challenges in radiation protection, both those that are newly emerging concerns and those that are somewhat more mature; but they have not yet adequately met the challenge. Finally, the word "meeting" is our action word in the theme, and indicates hopefully that we are taking some positive action toward scoping today's challenges toward laying out a plan of attack, reporting on our preliminary findings and evaluations, and eventually moving towards a final accomplishment.

I would like to briefly review some of the events in the week in the context of the theme. Overall, I think the program followed the theme quite well. The keynote address by Dr. Margaret Maxey on Sunday afternoon was, in my opinion, excellent. To me, it was refreshing to hear someone discuss in a positive fashion and with real enthusiasm what we need to be concerned with in radiation protection rather than the usual what is wrong or bad about radiation. The somewhat controversial sessions on mammography and CT scanning were certainly apropos to a discussion of today's challenges. And the open forum (if you remember, the open forum had a menu of wine, cheese, and radiologists) gave us an opportunity to talk with someone besides our own close group about our mutual radiation control problems. I would like to see more such forums at future annual meetings perhaps with different groups of allied professionals with whom we share mutual radiation concerns.

The task forces, which we recognize are the backbone of the Conference, worked throughout the year as well as at the annual meeting. These are where the detailed technical issues are discussed and hopefully, through implementation of the task force recommendations, the challenges can be met. If you will notice the number of task forces increased this year, and this is indicative of the fact that I think the number of today's challenges have increased. I think I speak for all three sponsoring Federal agencies and also the National Bureau of Standards when I say that the efforts put forth voluntarily by you State people in working on the task forces provide a vital input to our, or I should say "your," Federal programs. And I think we are getting this at a bargain price.

If you notice, this year in the program we had to go to concurrent technical sessions; again, indicative of the fact that the number of radiation protection challenges are increasing. The early speakers this afternoon addressed not only today's radiation protection challenges, but problems which we have today that resulted from our failure, perhaps, to meet yesterday's challenges. Our colleagues from the public interest sector gave us a few blasts of criticisms. They told us some things we were doing right, some things we were not doing enough of, some things we were doing wrong, both Federal and State. I think sometimes we do not like to hear what the public interest sector has to say to us. Sometimes we do not agree with what they say, but I think we need to listen to them and hear their side of the story to make sure that we indeed are meeting today's challenges.

As an overall assessment, I think the technical content of this meeting was perhaps the best we have ever had. In my mind, it was current, concise, interesting, thought-provoking, informative, and certainly enjoyable. I believe this 9th annual conference will have a positive impact on meeting today's challenges.

In conclusion, I want to add my personal thanks to those that Shelly gave to the Washington people, both the State and Federal people here in Seattle, to members of the Executive Board who made this meeting the success that I think it is and was, and from Bill Rowe, our Deputy Assistant Administrator, our headquarters and laboratory staff of the Office of Radiation Programs, and our EPA regional radiation representatives who are here, I want to say thanks to you members of the Conference for this oppoortunity to continue this demonstration of a partnership. This partnership is between the State and Federal agencies, and to our mind it is a partnership that really works.

MR. MILLER: I am happy to say that I do not have any studies or surveys to report on. Likewise, you now know why we put Shelly on first, because we thought no one would be left by the time the rest of us got up to speak.

As you all know, the weather has been great, the facilities have been super, the technical meetings superior, and the social aspects outstanding. This has been a great meeting to cap off Bob Will's last year with the Board of Directors in his dual role as the program chairman and your host. Any of you who have been involved in a meeting of this size know this means a tremendous amount of work. But the results have been superb.

There are many people to be thanked, and I just want to repeat what Shelly and Bob have already said to Bob Will, Marian, and their children, and the staff of the Washington Radiation Program, Dave and Lucy Flora, the FDA staff, and Ed Cowan, his wife, and if I have left anyone else out, I am sorry, but you have all done a superb job. I would also like to thank the speakers and clinicians for their professional and technical contributions to this meeting; they were high quality and superb. I believe Bob Augustine covered that all very well.

This meeting really boils down to another outstanding example of success and accomplishment as a result of hard work and dedication by those I have already mentioned, but there was also a lot of work by the sponsoring Federal agencies and your Executive Committee. So, on behalf of the Food and Drug Administration, especially the Office of the Commissioner, the Bureau of Radiological Health, and the Executive Director for Regional Operations, I want to compliment you all for your contributions to this delightful and informative Ninth Annual Meeting.

Meeting Today's Challenges is not the only theme of the meeting this week, but the question we wrestle with every day on how to best respond to our mission of protecting the public health from the many ramifications in the radiation area with our limited resources. I believe this meeting helped us to establish priorities when we return home. I have had nothing but good vibes from all of you this meeting; you know, we have made some changes this year which seem to have paid off. We covered a lot of ground and we have learned a lot. During this meeting, your Executive Committee has been hard at work as you have heard. I can only repeat that Jerry Parker has done an outstanding job, but then, that is expected. He has been doing that for the last 9 years.

I would like to congratulate Alice Dolezal on her appointment as Chairperson elect. Alice is one of the hardest working individuals in the entire Conference that I have seen over the years. I also welcome Dave Lacker to the Executive Committee, which pleases me very much.

I am looking forward to next year's meeting in Harrisburg. I have been over there and looked over the facilities, and they are outstanding. If you thought these were great, you will be very pleased with those in Harrisburg.

In closing, I would just like to say that a conference of this type is like a chain. It is only as strong as its weakest link. So, you all have to work together to make sure all these links remain strong. We may, as a Conference, have any handicap, but the only one we can't overcome is a loss of backbone. You have to stand up and speak up for what you believe in. It has been a great meeting and I thank you all for your contributions.

MR. McHARD: I believe that the three Federal liaison representatives have done an excellent job of summarizing the meeting, and I certainly can't add anything to that other than what I have already noted. However, there are a few things that traditionally are accomplished at this time. The first of these that I would like to do is to acknowledge the visitors we have at this meeting from our neighbors to the north and our neighbors to the south; namely, the Dominion of Canada and the United States of Mexico. We have here from Canada, Patrick Barrett, from Edmonton, Alberta; Sunil Choubal, from Saskatoon, Saskatchewan; Dr. Wang Greene from Vancouver, British Columbia; A.J. "Tony" MacKay, from Regina, Saskatchewan; and Kent Humphrey, from Vancouver, British Columbia. And from Mexico, from Mexico City, we have Dr. Isabel Galvin. We do appreciate you attending this meeting and we hope, through your attendance, that it has been helpful to you and to your programs from your countries. We certainly enjoy the interplay and the dialogue that occurs at the meetings between those of you from foreign countries and those of you here in the United States of America. We feel, and I hope that you feel, that our problems are very similar and therefore it is very fitting that you attend our meeting and get the benefit of it.

Next, I would like to make a few remarks of my own concerning all of those who put out a great deal of effort to make this meeting possible. I think until you have gone through it, until you have been a part of presenting a meeting like this, you have no concept of all the effort that goes into it. It is quite a task to make all the arrangements and do all the physical labor and all the mental gymnastics that are required to see that a meeting comes to fruition and proceeds smoothly through a whole week. We had about 370 people in attendance here counting spouses and children. So, that is a rather large meeting to arrange for, and to handle. First, I would like to acknowledge with thanks and gratitude on behalf of the Executive Board and the Conference the local host, State host, Bob and Marian Will. You did a great job and we thank you. Also, the two Federal hosts, Dave and Lucy Flora and Ed and Pat Cowan.

Then, in addition to those hosts, we had a number of other people that I would like to recognize. And, again, on behalf of the Executive Board and Conference we want to thank all of you, including these, if I somehow failed to get your names, so, I might not read it. But from the Washington State staff is Lee Gronemeyer, Ellen Haars, Nancy Kirner, Grover Nelson, Dean Osterud, Paul Snyder, and Dick Warner. And from the Federal offices here in Seattle, Jim Davis and Bill Van Pelt. Those who helped with the business office and registration were Linda Chalmers, who is Jerry Parker's secretary back in Massachusetts; Nancy Braun, Betty Ford, Jan Benestro, Linda Vernon, Bettye Swanson, who is the Conference secretary, and Marian Will. Helping with the spouse program was Lucy Flora, Jan Van Pelt, Pat Cowan, Clara Davis, Jan Osterud, and Marian Will. And those that helped with the youth program, Jaunita Wood, March Will, Tim Trimbly, and Mary Packard.

That brings me to my comments about the week, the meeting here. I think along with the others who have been up here and commented on the program, that it is rather obvious that this was quite a successful meeting. The technical program was excellent. I might mention that about 41 percent of the papers were presented by State representatives. From the Executive Board's viewpoint, we thought that was a good thing. I don't believe we can overstate just how successful this meeting was. The social activities were excellent, there was some memorable moments, and I suppose those moments are different for everybody here.

I think the sessions on Monday, including the dialogues with ACR at 5:30 were an excellent move and an excellent item to have been included within the agenda. It was very helpful, I feel, and our report that we got back from everyone who attended was that everyone who did attend thought it was an excellent presentation.

Secondly, I think that our video theater, which was brought here by BRH, and the fact that this Conference was able to have a television station of its own which broadcast for 24 hours a day on Channel 3, is quite a remarkable accomplishment. The information that was put out over that video theater was quite remarkable. I don't know how many of you spent any time looking at Channel 3, but I did a little bit, what time I could. Every time I turned it on, the kids said, "Daddy, you're not going to look at Channel 3 again, are you?" Nevertheless, it was an excellent part of the program, I thought, and deserves mention here.

Another thing that I might point out that was new this year was that we had the open meetings of all the task forces on Tuesday afternoon. And from the reports that the Executive Board got, this was well recieved. We recognize that there are a few problems involved in doing this, but we believe at the moment that the benefits of this type of program far outweigh any negative effects.

The fourth item that deserves mention, which is new this year for this Conference, were concurrent sessions. As I believe Bob Augustine mentioned, it is quite apparent that for us to hold this meeting to a 4 or 5 day meeting with the number of papers and subjects that we should or would like to present and that are topical in nature, we almost are forced to go to concurrent sessions. And, again, the reports we got from the Executive Board were that by and large the participants felt this was a good thing. It allowed people to make a choice and it allowed them to be occupied. In other words, they had a choice to go to a session, whereas before, if they did not like the particular subject that was being presented, they had no technical sessions to choose from. So, all in all, I feel it was an excellent program and the committee will try to do our best to improve on it for next year in Harrisburg.

Speaking of Harrisburg, I will announce that the Tenth Annual Meeting of the Conference will be held in Harrisburg, Pennsylvania, from April 30 through May 5, 1978.

It is traditional at this time also to make an informal introduction of the new officers of the Conference whose election was announced and certified at yesterday's business meeting.

Our new officers are Alice Dolezal, who is the Chairwoman-Elect; and Dave Lacker, who is the new member on the Executive Board from Texas.

MR. JOHNSON: Mr. Chairman, I think the Conference ought to go on record as addressing our appreciation to friends of the Conference, and specifically Chem-Nuclear systems for the Monday night evening.

MR. McHARD: Yes; thank you for reminding me of that. We certainly do appreciate the assistance of those private concerns who did sponsor certain aspects of the meeting. If there are no other matters, I declare the Ninth Annual Conference on Radiation Control adjourned.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1978 O - 259-883

The ABSTRACT CARDS below are designed to facilitate document retrieval using Coordinate Indexing. They provide space for an accession number (to be filled in by the user), suggested keywords, bibliographic information and an abstract.

The Coordinate Index concept of reference material filing is readily adaptable to a variety of filing systems. Coordinate Indexing is described in the publication "IBM Data Processing Techniques - Index Organization for Information Retrieval" (C 20 8062). Copies are available through IBM Branch Offices.

The cards are furnished in triplicate to allow for flexibility in their use (for example, author card index, accession number card index).

Accession No.

Sponsors: Conference of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, Food and Drug Administration, HEW; Office of Radiation Programs, Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. 9TH ANNUAL NATIONAL CONFERENCE ON RADIATION CONTROL--Meeting Today's Challenges.

U.S. Department of Health, Education, and Welfare, PHS, FDA, Bureau of Radiological Health - HEW Publication (FDA) 78-8054 (April 1978) 416 pp. (limited distribution).

ABSTRACT: This publication contains the proceedings of the 9th Annual National Conference on Radiation Control-Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference

(over)

Accession No.

Sponsors: Conference of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, Food and Drug Administration, HEW; Office of Radiation Programs, Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. 9TH ANNUAL NATIONAL CONFERENCE ON RADIATION CONTROL--Meeting Today's Challenges.

U.S. Department of Health, Education, and Welfare, PHS, FDA, Bureau of Radiological Health - HEW Publication (FDA) 78-8054 (April 1978) 416 pp. (limited distribution).

ABSTRACT: This publication contains the proceedings of the 9th Annual National Conference on Radiation Control-Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference

(over)

Accession No.

Sponsors: Conference of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, Food and Drug Administration, HEW; Office of Radiation Programs, Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. 9TH ANNUAL NATIONAL CONFERENCE ON RADIATION CONTROL--Meeting Today's Challenges.

U.S. Department of Health, Education, and Welfare, PHS, FDA, Bureau of Radiological Health - HEW Publication (FDA) 78-8054 (April 1978) 416 pp. (limited distribution).

ABSTRACT: This publication contains the proceedings of the 9th Annual National Conference on Radiation Control-Meeting Today's Challenges, held June 19-23, 1977, in Seattle, Washington. Sponsors were the Conference

(over)

of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces are included in these proceedings.

KEYWORDS: Atomic Energy Act; BENT; CT scanning; genetically significant dose (GSD); laser; mammography; nonionizing; nuclear medicine; personnel dosimetry; quality assurance; radiation; risk factor; ultrasound; x ray.

---

of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces are included in these proceedings.

KEYWORDS: Atomic Energy Act; BENT; CT scanning; genetically significant dose (GSD); laser; mammography; nonionizing; nuclear medicine; personnel dosimetry; quality assurance; radiation; risk factor; ultrasound; x ray.

---

of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces are included in these proceedings.

KEYWORDS: Atomic Energy Act; BENT; CT scanning; genetically significant dose (GSD); laser; mammography; nonionizing; nuclear medicine; personnel dosimetry; quality assurance; radiation; risk factor; ultrasound; x ray.

FDA 77-8026	Symposium on Biological Effects and Measurement of Radio Frequency/Microwaves. (GPO 017-015-00137-7, $5.25) (PB 272 906/AS, mf only).
FDA 77-8028	Diagnostic Radiology Quality Assurance Catalog (GPO 017-015-00127-0, $4.00) (PB 271 248/AS, mf only).
FDA 77-8029	Course Manual for Machine Sources of X Rays (GS-461) (GPO 017-015-00131- 8, $4.00) (PB 272 011/AS, mf only) (supersedes FDA 73-8026).
FDA 77-8030	Course Manual for X-Ray Measurements (GS-462) (GPO 017-015-00130-0, $3.50) (PB 272 012/AS, mf only) (supersedes FDA 73-8027).
FDA 77-8031	Course Manual for X-Ray Applications (GS-463) (GPO 017-015-00132-6, $3.00) (PB 272 010/AS, mf only) (supersedes FDA 73-8028).
FDA 77-8032	The Bureau of Radiological Health...A Look at FDA's Program to Protect the American Consumer from Radiation (GPO 017-015-00128-8, $1.20) (PB 272 869/AS, mf only).
FDA/77-8033	BRH Publications Index (GPO 017-015-00129-6, $4.25) (PB 271 734/AS, mf only).
FDA 77-8034	Report of State and Local Radiological Health Programs, FY 1976 (PB 273 392/AS, $5.25).
FDA 77-8035	The Developing Role of Short-Lived Radionuclides in Nuclear Medicine (GPO 017-015-00139-3, $2.00) (PB 272 298/AS, mf only).
FDA 77-8036	Second Image Receptor Conference: Radiographic Film Processing (GPO 017-015-00134-2, $3.00) (PB 273 287/AS, mf only).
FDA 77-8037	Procedures for Field Testing Microwave Ovens (GPO 017-015-00138-5, $1.60) (supersedes FDA 73-8016) (PB 272 839/AS, mf only).
FDA 77-8039	Exposure and Processing Guide for Dental Radiography (GPO 017-015-00135-1 $1.20).
FDA 77-8042	CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1976 (PB 273 560/AS, $6.50).
FDA 78-8015	Progress in Radiation Protection 1976.
FDA 78-8027	Directory of Personnel Responsible for Radiological Health Program (supersedes FDA 77-8027).
FDA 78-8043	A Review of the Use of Ionizing Radiation for the Treatment of Benign Diseases (GPO 017-015-00141-5, $2.10) (PB 274 032/AS, mf only).
FDA 78-8044	Federal Recordkeeping Requirements for Television Receiver Dealers and Distributors (GPO 017-015-00142-3, $0.50/3.75 per 100).
FDA 78-8047	Source Book of Educational Materials for Medical Radiographers (GPO 017-015-00143-1, $2.50) (PB 275 953/AS, mf only).
FDA 78-8048	Symposium on Biological Effects and Characterizations of Ultrasound Sources (GPO 017-015-00145-8, $4.25).
FDA 78-8049	Measurements of the Performance Parameters of Gamma Cameras: Part I (GPO 017-015-00144-0, $2.20).